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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

RITE AID CORPORATION, RITE AID HDQTRS. CORP., JCG (PJC) USA, LLC, MAXI DRUG, INC. D/B/A BROOKS PHARMACY, and ECKERD CORPORATION,	:	CASE NO.
Plaintiffs,	:	**JURY TRIAL DEMANDED**
vs.	:	
PFIZER INC., PFIZER IRELAND PHARMACEUTICALS, WARNER-LAMBERT COMPANY, WARNER-LAMBERT COMPANY LLC, RANBAXY INC., RANBAXY PHARMACEUTICALS, INC. and RANBAXY LABORATORIES LIMITED,	:	
Defendants.	:	

COMPLAINT AND DEMAND FOR JURY TRIAL

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Plaintiffs Rite Aid Corporation, Rite Aid Hdqtrs. Corp., JCG (PJC) USA, LLC, Maxi Drug, Inc. d/b/a Brooks Pharmacy and Eckerd Corporation, whose addresses appear in paragraphs 30 through 31 below, (collectively "Plaintiffs") bring this civil action against Defendants Pfizer Inc., Pfizer Ireland Pharmaceuticals, Warner-Lambert Company, Warner-Lambert Company LLC, Ranbaxy, Inc, Ranbaxy Pharmaceuticals, Inc. and Ranbaxy Laboratories Limited under the antitrust laws of the United States. For their Complaint, Plaintiffs allege as follows:

I. INTRODUCTION

1. This is a civil antitrust action challenging an unlawful and anticompetitive scheme by Defendants to maintain monopoly power and delay the entry of generic versions of the blockbuster brand-name drug Lipitor. Although the original compound patent for Lipitor expired March 24, 2010, generic entry did not occur until November 30, 2011, over 20 months later. The Pfizer Defendants[1] illegally caused this delay by implementing an overarching anticompetitive scheme, which included:

a. perpetrating fraud upon the United States Patent and Trademark Office ("PTO") to procure Patent No. 5,273,995 (the '995 Patent), which the Pfizer Defendants thereafter wrongfully listed in the United States Food and Drug Administration's ("FDA") "Orange Book";

b. filing a sham "citizen petition" with the FDA;

c. instituting objectively baseless "sham" litigation against Ranbaxy with respect to the fraudulently-procured '995 Patent and certain "process" patents;

d. entering into an unlawful market allocation agreement with defendant

[1] The "Pfizer Defendants" are Pfizer Inc., Pfizer Ireland Pharmaceuticals, Warner-Lambert Company, and Warner-Lambert Company LLC.

Ranbaxy,[2] pursuant to which Ranbaxy agreed not to launch (or permit other companies to launch) a generic version of Lipitor in the United States until November 30, 2011 in exchange for various forms of consideration from the Pfizer Defendants (the "Agreement"); and

e. pursuant to and in furtherance of the Agreement, thwarting other generic companies' efforts to obtain judicial declarations that the Pfizer Defendants' various unasserted patents were invalid, unenforceable and/or would not be infringed by generic Lipitor, in order to avoid the triggering of Ranbaxy's anticipated 180-day first-to-file marketing exclusivity and thereby sustain the Pfizer Defendants' and Ranbaxy's ability to, in concert, block other generic companies from launching generic Lipitor earlier than November 30, 2011.

2. The scheme worked as planned. Generic Lipitor was not sold until on or about November 30, 2011, far later than it would have been sold absent Defendants' illegal, anticompetitive conduct.

3. Because of Defendants' scheme to delay generic Lipitor competition, in whole or in part, Plaintiffs have paid hundreds of millions of dollars more for atorvastatin calcium than they would have paid absent such conduct.

The Pfizer Defendants' Fraudulently-Obtained '995 Patent

4. In 1987, Warner-Lambert obtained the original compound patent for Lipitor, U.S. patent 4,681,893 (the "'893 Original Lipitor Patent" or "'893 Patent"). The '893 Patent claimed patent protection for various enantiomer forms of atorvastatin, including the isolated enantiomer which, when formulated into a calcium salt, is Lipitor. After various extensions obtained by Pfizer, the '893 Patent expired on March 24, 2010.

5. In 1989, Warner-Lambert sought even longer patent exclusivity for Lipitor. It applied for a patent specifically claiming the isolated enantiomer used to formulate Lipitor,

[2] "Ranbaxy" refers to Ranbaxy Inc., Ranbaxy Pharmaceuticals Inc., and Ranbaxy Laboratories Limited.

including the calcium salt of that enantiomer. Warner-Lambert eventually obtained this patent, which originally issued as the '995 Patent. This patent ultimately extended the Pfizer Defendants' Lipitor monopoly until June 28, 2011. As detailed below, however, the Pfizer Defendants obtained the '995 Patent only by defrauding the PTO.

6. For example, to circumvent an obviousness objection, Warner-Lambert represented that it had unexpectedly discovered that the isolated enantiomer was ten times more effective in inhibiting the production of cholesterol than the racemate containing the enantiomer and its mirror image molecule, rather than two times more effective, as a person of ordinary skill in the art would expect. This representation was false because, as Warner-Lambert knew, the data submitted to the PTO as purported support for this "surprising" discovery was a fabricated chart reflecting an unscientific mish-mash of data points that were intentionally selected from over a dozen separate tests performed on different formulations over a two-year period.

7. Thus, the purported invention that allegedly produced a *ten-fold* increase in activity of the isolated enantiomer (the R-trans enantiomer) over the previously patented racemate did not exist. In fact, as Warner-Lambert knew, the data, analyzed pursuant to sound and reasonable scientific principles, established that the invention claimed in the '995 Patent (the isolated R-trans enantiomer) provided only a *two-fold* increase in activity over the racemate -- exactly the result expected based on the prior art. The claim of a ten-fold increase in cholesterol-inhibiting activity was a fabricated falsehood, made only after Warner-Lambert lawyers instructed the lead scientist to go back through years of data and find something "surprising."

8. Similarly, a second data submission was based on a chemical test so methodologically flawed (*e.g.*, the drug wasn't even dissolved into a solution before testing) that no reasonable chemist would have relied on it to support the claimed ten-fold increase in activity.

9. Warner-Lambert's false representations were highly material. Indeed, they formed the only bases upon which the PTO granted the '995 Patent. Absent these false representations, the '995 Patent would not have issued.

10. Recent patent lawsuits in foreign jurisdictions reveal Warner-Lambert's abuses before the PTO. Indeed, courts in Australia and Canada have concluded that the '995 Patent was obtained as a result of these material misrepresentations to the PTO.[3]

11. While the Pfizer Defendants have attempted to avoid the consequences of this fraud by eschewing reliance on their earlier fraudulent data submitted to the PTO in seeking reissuance of the '995 Patent, they cannot avoid its significance. But for this fraud, the isolated enantiomer patent would not have issued in any form at any time, and would not have been available to support a lawsuit against would-be generic competitors to branded Lipitor. But for the fraud before the PTO in procuring the '995 Patent, generic atorvastatin calcium would have been available in the United States market well before November 30, 2011.

The Pfizer Defendants' Sham "Citizen" Petition

12. Ranbaxy filed the first abbreviated new drug application ("ANDA") with the FDA seeking to market generic Lipitor on August 19, 2002. The Pfizer Defendants sued Ranbaxy for infringement of the '893 Patent and the fraudulently-procured '995 Patent in February of 2003. By operation of statute, the Pfizer Defendants' lawsuit prevented the FDA from approving Ranbaxy's ANDA for a 30-month period, expiring in or around August of 2005.

13. Just before the 30-month stay was to expire, the Pfizer Defendants -- knowing that the FDA could grant final approval to Ranbaxy's generic Lipitor ANDA after the 30-month stay

[3] These decisions post-date a decision to the contrary in the District of Delaware. Upon information and belief, the foreign decisions revealed the full extent of the Pfizer Defendants' fraud, which was not completely disclosed to the Delaware court.

expired, and fearful that the FDA would do so -- took additional steps to try to delay the FDA's action on Ranbaxy's ANDA. Specifically, the Pfizer Defendants sent a letter to the FDA on July 28, 2005 (which they re-filed as a so-called "citizen petition" on November 7, 2005), asserting without any regulatory, scientific, medical, or other reasonable basis that the FDA should, in reviewing generic Lipitor ANDAs, take the time to consider information that bore no reasonable relationship to the approvability of any generic Lipitor ANDA (the "Petition"). The Pfizer Defendants timed their submission of this objectively baseless letter and Petition to further delay final FDA approval of Ranbaxy's generic Lipitor ANDA, and not for any legitimate regulatory, scientific, medical or other legitimate purpose.

The Pfizer Defendants' Illegal Horizontal Market Allocation Agreement with Ranbaxy

14. While the Petition was pending, the district court found in the Pfizer Defendants' favor in the patent litigation against Ranbaxy. The Court of Appeals for the Federal Circuit affirmed that judgment as to the '893 Patent, but reversed as to the '995 Patent, the relevant claim of which the Federal Circuit invalidated. While the Pfizer Defendants sought reissuance of the '995 Patent, the Pfizer Defendants and Ranbaxy entered into the Agreement, and Ranbaxy thereby became a co-conspirator with the Pfizer Defendants in the overarching anticompetitive scheme.

15. As the first filer of an ANDA for generic Lipitor prior to December of 2003, Ranbaxy was entitled to market its generic Lipitor for 180 days free from competition from other ANDA filers. This would give Ranbaxy the corresponding ability -- simply by refraining from launching its own generic Lipitor or from relinquishing the right to its 180-day exclusivity period -- to prevent other ANDA competitors from entering the United States market. All the Pfizer Defendants needed to do to prevent all generic Lipitor competition was to enter into an agreement with Ranbaxy not to compete. Such an agreement between the Pfizer Defendants and Ranbaxy

would create a nearly-insurmountable obstacle to generic competition for all ANDA filers for the duration of such an agreement.

16. That is just what the Pfizer Defendants and Ranbaxy did. In 2008, after claim 6 of the Pfizer Defendants' '995 patent had been invalidated in litigation with Ranbaxy, Pfizer and Ranbaxy entered into the Agreement. The Agreement constituted an unlawful contract, combination and conspiracy to allocate the entire United States market for atorvastatin calcium to the Pfizer Defendants until November 30, 2011.

17. Pursuant to the Agreement, Ranbaxy agreed that it would neither (a) compete directly with Pfizer with a generic Lipitor in the United States market, nor (b) selectively waive or relinquish its first-to-file 180-day marketing exclusivity so as to permit any other ANDA filer to compete directly against the Pfizer Defendants with a generic Lipitor in the United States market until November 30, 2011.

18. In exchange for Ranbaxy's agreement not to launch (or authorize another ANDA filer to launch) generic Lipitor in the United States until November 30, 2011, the Pfizer Defendants gave Ranbaxy significant consideration, including dismissal of a damage claim on a product that Ranbaxy had launched at risk and the right to market generic Lipitor in at least eleven foreign markets.

19. The Pfizer Defendants also purported to give Ranbaxy protection from infringement liability in connection with a variety of patents, but that "consideration" was illusory, and merely inserted into the Agreement to disguise the illegal horizontal agreement to allocate to the Pfizer Defendants the entire United States market for atorvastatin calcium. In fact, as detailed below, no patent related to Lipitor had any legitimate exclusionary power or potential to exclude generic versions of Lipitor past March of 2010, when the '893 Patent expired.

20. Indeed, as the Pfizer Defendants well knew, the '995 Patent was obtained through fraud on the PTO, and the Pfizer Defendants could not have used any legitimately-obtained patent to obtain a court order enjoining Ranbaxy (or any other relevant ANDA filer) from making or selling generic Lipitor after March 24, 2010. An infringement case against Ranbaxy (or any other ANDA filer) based upon any legitimately-obtained Lipitor patent that expired after March 24, 2010 would have been (and was, with respect to, for example, Pfizer's suit claiming infringement of Pfizer's process patents) an objectively baseless sham. (And even if, *arguendo*, the '995 Patent was obtained legitimately, it expired by June 28, 2011, five months before November 30, 2011.) Furthermore, neither the Pfizer Defendants nor Ranbaxy subjectively believed there was any threat of infringement from such patents. As a result, the Agreement gave the Pfizer Defendants protection from generic Lipitor competition beyond the exclusionary power and potential of any Lipitor patents.

The Obstruction of Later Generic Entrants

21. As the Pfizer Defendants and Ranbaxy knew and intended, the Agreement sought to prevent other ANDA filers from launching their own generic versions of Lipitor before Ranbaxy. Ranbaxy's 180-day first-to-file marketing exclusivity as the first filer of a generic Lipitor ANDA generally meant that only Ranbaxy's commercial marketing of its ANDA product would trigger the 180-day period, only after which other generic Lipitor ANDA filers could be approved by the FDA. But there were two possible exceptions.

22. One exception was that Ranbaxy's first-to-file exclusivity could be triggered by one or more court decisions obtained by Ranbaxy or another ANDA filer that the patents listed in the FDA "Orange Book" as claiming Lipitor were invalid or not infringed. If Ranbaxy or another ANDA filer obtained such a court decision, Ranbaxy's 180-day first-to-file marketing exclusivity would have commenced running, even if Ranbaxy had not yet begun commercial marketing of its

ANDA product. Another exception was if the FDA could be convinced to deprive Ranbaxy of the 180-day exclusivity and approve the ANDAs of other generic companies unimpeded by the 180-day period.

23. These exceptions were of substantial concern to the Pfizer Defendants and Ranbaxy in 2008, when they reached the Agreement. The Pfizer Defendants did not want generic Lipitor competition earlier than the November 30, 2011 date provided in the Agreement, and Ranbaxy did not want any involuntary triggering or forfeiture of its anticipated, and enormously valuable, 180-day first-to-file marketing exclusivity. Such events would frustrate the Agreement, and threaten to diminish or eliminate the value of Ranbaxy's exclusivity. Both the Pfizer Defendants and Ranbaxy had a keen interest in ensuring that Ranbaxy's 180-day exclusivity operated to prevent other ANDA applicants for generic Lipitor from coming to market.

24. To prevent the involuntary triggering of Ranbaxy's 180-day first-to-file marketing exclusivity prior to November 30, 2011, the Pfizer Defendants, pursuant to and in furtherance of the Agreement, opposed the efforts of any other generic ANDA filer to obtain a determination that the patents listed in the FDA "Orange Book" as covering Lipitor were invalid or would not be infringed by the marketing of any ANDA filer's generic Lipitor. They did so by attempting to create legal obstacles to such determinations and by settling lawsuits brought by other ANDA filers before such determinations could occur.

25. These efforts worked. Despite repeated efforts, no ANDA filer was able to circumvent the Agreement between the Pfizer Defendants and Ranbaxy by triggering Ranbaxy's 180-day marketing exclusivity prior to November 30, 2011.

The Harm to Competition

26. Were it not for Defendants' overarching anticompetitive scheme to delay generic Lipitor competition in the United States, in whole or in part, generic Lipitor would have been

available in the United States far earlier than November 30, 2011.

27. But for Defendants' illegal conduct, Plaintiffs would have begun to pay less for their atorvastatin calcium requirements far earlier than on or about November 30, 2011. As a result, Defendants, by their conduct, injured Plaintiffs by causing them to pay substantial overcharges -- potentially in the billions of dollars -- on their purchases of atorvastatin calcium.

II. JURISDICTION AND VENUE

28. This action arises under sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, and section 4 of the Clayton Act, 15 U.S.C. § 15(a), to recover threefold damages, costs of suit and reasonable attorneys' fees for the injuries sustained by Plaintiffs resulting from Defendants' unlawful foreclosure of the United States market for atorvastatin calcium. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1337(a).

29. Defendants transact business within this district and/or have an agent and/or can be found in this district. Venue is appropriate within this district under section 12 of the Clayton Act, 15 U.S.C. § 22, 28 U.S.C. §1391(b) and (c) and 28 U.S.C. §1407.

III. PARTIES

30. Plaintiffs Rite Aid Corporation and Rite Aid Hdqtrs. Corp. (collectively "Rite Aid"), are corporations organized and existing under the laws of the State of Delaware with a principal place of business at 30 Hunter Lane, Camp Hill, Pennsylvania 17011. Rite Aid purchases substantial quantities of pharmaceutical products and other goods for resale to the public through more than 4,600 drugstores operated by its affiliates. Rite Aid brings this action on its own behalf and as the assignee of McKesson Corporation, which purchased Lipitor directly from the Pfizer Defendants during the relevant period for resale to Rite Aid.

31. Plaintiff JCG (PJC) USA, LLC ("JCG USA") is a Delaware limited liability corporation with a principal place of business in Camp Hill, Pennsylvania. On June 4, 2007, JCG

USA became a wholly-owned subsidiary of Rite Aid Corporation. JCG USA is the parent corporation of Plaintiffs Maxi Drug, Inc. d/b/a Brooks Pharmacy ("Brooks") and Eckerd Corporation ("Eckerd"), both of which are Delaware corporations. JCG USA, Brooks, and Eckerd hereafter are collectively referred to as "Brooks/Eckerd." Brooks/Eckerd purchases substantial quantities of pharmaceutical products and other goods for resale to the public through its retail stores. Brooks/Eckerd brings this action on its own behalf and as the assignee of McKesson Corporation, which purchased Lipitor directly from the Pfizer Defendants during the relevant period for resale to Brooks/Eckerd.

32. Defendant Pfizer, Inc. is a corporation organized and existing under the laws of the State of Delaware with a place of business at 235 East 42nd Street, New York, New York 10017. At all relevant times, Defendant Pfizer, Inc. engaged in the conduct challenged in this case and attributed to the Pfizer Defendants, itself and/or through its various employees and/or other agents acting within the course and scope of their duties and/or with actual, apparent, or ostensible authority in connection therewith.

33. Defendant Pfizer Ireland Pharmaceuticals, formerly known as Warner Lambert Export, Ltd., is a partnership organized and existing under the laws of Ireland, with registered offices at Pottery Road, Dun Laoghaire, Co. Dublin, Ireland. Pfizer Ireland Pharmaceuticals, a wholly-owned indirect subsidiary of defendant Pfizer, Inc., is the exclusive licensee of the '995 Patent and other patents. At all relevant times, defendant Pfizer Ireland Pharmaceuticals engaged in the conduct challenged in this case and attributed to the Pfizer Defendants, itself and/or through its various employees and/or other agents acting within the course and scope of their duties and/or with actual, apparent, or ostensible authority in connection therewith.

34. Defendant Warner-Lambert Company is a corporation formerly organized under the laws of the State of Delaware with offices for service of process at 235 East 42nd Street, New York,

New York 10017. In 1997, Warner-Lambert and Pfizer began co-promotion of Lipitor. On June 19, 2000, Pfizer completed its merger with Warner-Lambert whereby Pfizer purchased all outstanding shares of Warner-Lambert common stock. Each share of Warner-Lambert stock was converted into 2.75 shares of Pfizer common stock. The merger qualified as a tax-free reorganization and was accounted for as a pooling of interests. Warner-Lambert Company became a wholly-owned subsidiary of Pfizer Inc. At the end of 2002, Warner-Lambert Company became a Delaware limited liability company and changed its name to Warner-Lambert Company LLC. Warner-Lambert knowingly controlled all activities of the applicant before the PTO in connection with the prosecution of the '995 Patent and other patents.

35. Warner-Lambert Company and Warner-Lambert Company LLC are collectively referred to as "Warner-Lambert." "Warner-Lambert" includes, but is not limited to, Warner-Lambert employees Bruce D. Roth, Joan Thierstein, Elizabeth M. Anderson, and Jerry F. Janssen.

36. Together, the defendants identified in the preceding four paragraphs are referred to herein as the "Pfizer Defendants."

37. Defendant Ranbaxy, Inc. is a corporation organized and existing under the laws of the State of Delaware, and has a place of business located at 600 College Road East, Princeton, New Jersey, 08540.

38. Defendant Ranbaxy Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, and has a place of business located at 600 College Road East, Princeton, New Jersey, 08540.

39. Defendant Ranbaxy Laboratories Limited is a corporation organized and existing under the laws of India, with a principal place of business located at Plot 90, Sector 32, Gurgaon-122001 (Haryana), India. At all relevant times, Defendants Ranbaxy Inc. and Ranbaxy

Pharmaceuticals Inc. acted in their own right and as agents of Defendant Ranbaxy Laboratories Limited.

40. Together, the defendants identified in the preceding three paragraphs are referred to herein as "Defendant Ranbaxy" or simply "Ranbaxy."

41. All of Defendants' actions described in this complaint are part of, and in furtherance of, the illegal monopolization and restraint of trade alleged herein, and were authorized, ordered, and/or done by Defendants' various officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs, within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of Defendants.

IV. LEGAL BACKGROUND

A. The Regulatory Structure for Approval of Generic Drugs and Substitution of Generics for Brand Name Drugs

42. Under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-392 ("FDCA"), a manufacturer of a new drug must obtain FDA approval to sell that new drug. The manufacturer must file a New Drug Application ("NDA") that includes data showing the drug is safe and effective as well as information about applicable patents.

43. After approval of an NDA, the brand manufacturer may list any patents that it believes could reasonably be asserted against a generic manufacturer who makes, uses, or sells a generic version of the brand name drug prior to the expiration of the listed patents in an FDA publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"). The FDA relies on the brand name manufacturer for information concerning the validity and applicability of the patents to the brand name drug. The FDA performs only a ministerial function in listing patents in the Orange Book.

44. Patents issued after the FDA approves an NDA may be listed in the Orange Book as related to the NDA if the manufacturer certifies, *inter alia,* that the new patents claim either the approved drug (for compound patents), or approved methods of use (for method-of-use patents). The NDA holder is required to list any new patents within 30 days of issuance. 21 U.S.C. §§ 355 (b)(1) & (c)(2).

45. Generic manufacturers may file abbreviated applications, or ANDAs, that (i) rely on the scientific findings of safety and effectiveness included in the brand name drug manufacturer's original NDA, and (ii) show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand name drug (or, in other words, is bioequivalent to the brand name drug). Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) ("Hatch-Waxman").

46. To obtain FDA approval of an ANDA, a generic manufacturer must certify that the generic drug will not infringe any patents listed in the Orange Book. An ANDA must contain one of four certifications. A Paragraph IV certification states "that the patent for the brand name drug is invalid or will not be infringed by the generic manufacturer's proposed product."

47. If a generic manufacturer files a Paragraph IV certification, the brand name manufacturer may delay the final FDA approval of the ANDA by suing for patent infringement. If the brand name manufacturer initiates a patent infringement action against the generic filer within 45 days of receiving notification of the Paragraph IV certification, the FDA may not grant final approval to the ANDA until the earlier of (a) the passage of 30 months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. The FDA may grant "tentative approval" while the 30-month stay is pending, but cannot authorize the generic manufacturer to go to market.

48. As an incentive to spur generic companies to provide alternatives to branded drugs,

the first generic manufacturer to file a substantially complete ANDA containing a Paragraph IV certification gets a period of protection from competition with other ANDA filers for that drug. For Paragraph IV certifications made before December 2003, the first generic applicant is entitled to 180 days of market exclusivity, measured from its initial commercial marketing of the drug or court decisions determining that the patents for the branded drug listed in the FDA Orange Book are invalid or not infringed, whichever comes first.

49. The statutory rules in effect for ANDAs filed (and Paragraph IV certifications submitted) before December of 2003 create an opportunity for branded drug companies and first-filed ANDA applicants to collude to delay generic drug competition. A first-filed ANDA applicant can, in concert with the branded drug company, effectively "park" its 180-day exclusivity, and thereby create a "bottleneck" that prevents other ANDA applicants from coming to market indefinitely. The FTC has observed this potential and the anticompetitive effects that can result. Federal Trade Commission, Generic Drug Entry Prior to Patent Expiration, An FTC Study, at vi-xi (FTC July 2002).

50. It is generally not in a first-filed ANDA applicant's unilateral economic interest to park its 180-day exclusivity.

51. Brand name manufacturers have large financial incentives to: (a) list patents in the Orange Book, even if such patents are not eligible for listing; and (b) sue any generic competitor that files an ANDA with a Paragraph IV certification, even if the competitor's product does not actually infringe the listed patent(s) and/or the patents are invalid or unenforceable, in order to delay final FDA approval of an ANDA for up to 30 months.

B. The Benefits of Generic Drugs

52. Once a generic manufacturer establishes that its generic drug is bioequivalent to a corresponding branded drug, the FDA assigns an "AB" rating to the generic drug, permitting it to be

sold and also substituted for the brand name drug at the pharmacy counter. Typically, AB-rated generics are priced significantly below their branded counterparts. Upon the entry of additional generics, drug prices generally fall even further.

53. Generic competition enables purchasers to (a) purchase generic versions of the brand name drug at a substantially lower price than the brand name price, and (b) purchase the brand name drug at a reduced net price. Generic competition can result in billions of dollars in savings to consumers, insurers, and other drug purchasers.

54. All states permit (and some states require) pharmacists to automatically substitute a generic drug for the corresponding brand name drug unless the doctor has stated that the prescription for the brand name product must be dispensed as written. Until a generic manufacturer enters the market, no such substitution can occur and therefore the brand name manufacturer can charge supracompetitive prices profitably without material loss of sales volume. Consequently, brand name drug manufacturers have a strong interest in seeking to delay the introduction of generic competition into the market.

55. Many third party payors (such as health insurance plans and Medicaid programs) have adopted policies to encourage the substitution of AB-rated generic drugs for their branded counterparts. Many consumers routinely switch from a branded drug to an AB-rated generic drug once the generic becomes available. Consequently, AB-rated generic drugs typically capture a significant share of their branded counterpart's sales, causing a significant reduction of the branded drug's unit and dollar sales.

V. FACTS

A. Statins

56. Lipitor belongs to a class of drugs called statins. Discovered in the 1970s, statins lower cholesterol by inhibiting the liver enzyme 3-hydroxy 3-methylglutrayl-coenzyme A

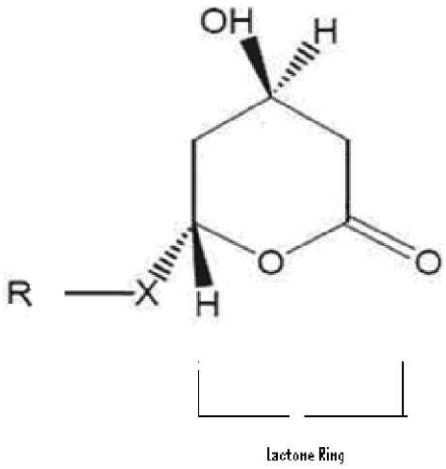
reductase ("HMG-CoA reductase"). HMG-CoA reductase controls the rate of the metabolic production of cholesterol; inhibiting HMG-CoA reductase inhibits the production of cholesterol. Common thinking is that high cholesterol is associated with coronary heart disease and atherosclerosis in some populations.

57. Efforts to reduce cholesterol levels are a big business: by 1997, five of the largest pharmaceutical companies marketed and sold six different brand name statins. In 2002, almost one in ten Americans aged 20 and older took a statin. In 2004, sales of statins topped $15.5 billion, comprising 6.6% of all prescription drug sales.

58. Branded statins cost between $2.50 and $5.00 a day ($75 to $150 a month, $900-$1,800 a year); generic statins cost markedly less, sometimes less than $1 a day.

59. Statins consist of three structural parts: a lactone ring, a linkage group (denoted as "X"), and a group or groups connected to the linkage group (referred to herein as an "R group").

Figure 1: Generalized Structure of Statins[4]

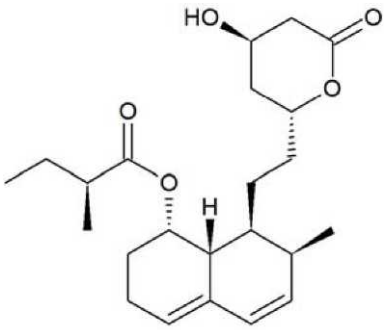


60. The R group for the well-known statins can contain one or more single rings or fused rings, and other substituent groups.

61. The lactone ring, on the right hand side, contains five carbons and one oxygen.[5] Attached to the ring and denoted as =O is an additional oxygen called a *ketone.* The lactone ring has two major substituents: a hydroxyl group (-OH) shown at the top of the ring, and the linkage group, X, attached to the R group. The two major substituents in the lactone ring are in a *trans* position; that is, the hydroxyl group is above the plane of the lactone ring and the linkage group X is below the plane of the lactone ring.

62. In the 1970s, researchers discovered that mevastatin, naturally occurring in red yeast and rice, inhibited cholesterol synthesis.

Figure 2: Mevastatin



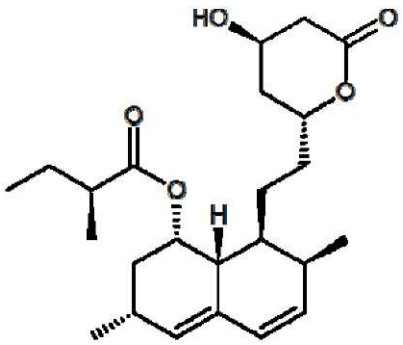
[4] The three-dimensional structure of molecules can be represented pictorially in two dimensions using the following symbols to represent the orientation of the atoms in space: (solid wedge) indicates that the molecule is projecting out of the page; (dashed wedge) indicates that the molecule is projecting behind the page; — (solid line) indicates that the molecule is in the plane of the paper.

[5] The lactone ring members are shown with the chemical convention that omits the carbon and some hydrogen atoms and shows only the bonds between the carbons and other atoms. Each carbon atom is designated as the point where two bond lines connect and each carbon is assumed to have to hydrogen atoms attached.

63. Mevastatin contains the lactone ring as shown in Figure 1 (top right of Figure 2), a linkage group, X (shown as ), and an R group of two fused rings with substituents. One of the fused rings contains a methyl group (-CH_3, shown as ) on the right ring and an additional O-linked substituent group on the left ring.

64. Around the same time, researchers discovered that lovastatin, naturally occurring in red yeast rice and oyster mushrooms, was another highly potent HMG-CoA reductase inhibitor. Merck sought and gained approval for Mevacor, a brand name version of lovastatin and the first statin available in the United States, in the early 1980s.

Figure 3: Lovastatin



65. The structure of lovastatin is similar to mevastatin. Lovastatin contains a lactone ring and a fused-ringed group joined to the lactone ring by a linkage group. The R group contains the same fused rings with same O-linked substituent group on the left ring and a methyl group on the right ring as found on mevastatin. Lovastatin has an additional methyl group.

66. In the early 1980s, Warner-Lambert sought to enter the market by developing a "me-too" version of the already-identified statins. Researchers at Warner-Lambert came up with a

formulation that used the same lactone ring as mevastatin and lovastatin but contained different linked substituents. Warner-Lambert called their new statin "atorvastatin."

B. Warner-Lambert Obtained the Original Lipitor Patent

67. On May 30, 1986, Warner-Lambert filed a patent application for a group of compounds and pharmaceutical compositions useful as hypercholesterolemic and hypolipidemic agents.[6] The patent application was entitled "*Trans-6-[2-(3- or 4-Carboxamido-Subsituted Pyrrol-1-yl)alkyl]-4-Hydroproxypyran-2-one Inhibitors Of Cholesterol Synthesis.*"

68. This application would eventually lead to the issuance of the '893 Patent.

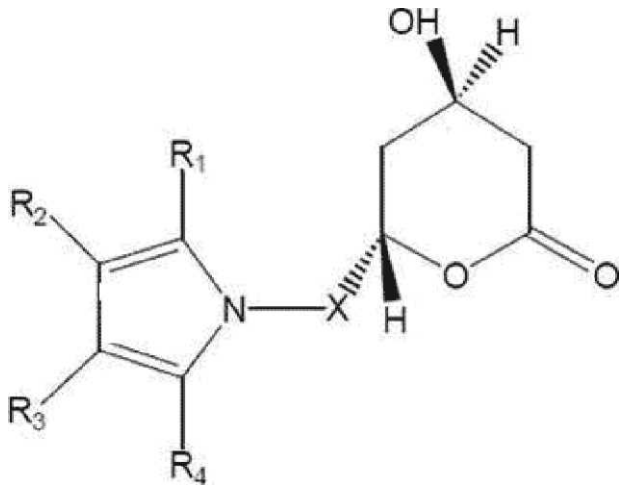
69. Because this lawsuit involves Warner-Lambert's fraudulent acquisition of another Lipitor patent *after* the issuance of the '893 Patent and fraudulent avoidance of the prior art contained in the '893 Patent, this Complaint now describes the background, claims, and uses of the '893 Patent next.

1. The Patent Specification Claims Atorvastatin, "the Corresponding Ring-Opened Acids Derived Therefrom" in Salt Form, and the R-trans and S-trans Enantiomers

70. Warner-Lambert stated in the patent specification for the Original Lipitor Patent that "in its broadest aspect the present invention provides compounds of structural formula I."

[6] The application was in the name of Bruce D. Roth. Dr. Roth was, at all relevant times, a leader of the drug discovery team at Warner-Lambert that developed Lipitor. He is the named inventor of Patent Nos. 4,681,893 and 5,273,995; the patent applicant for Patent Nos. 4,681,893 and 5,273,995; and the patent applicant in connection with the re-issuance proceedings for Patent No. 5,273,995. Patent Nos. 4,681,893 and 5,273,995 issued to Dr. Roth and were assigned to his employer, Warner-Lambert.

Figure 4: Warner-Lambert's Structural Formula I



71. Like other statins, structural formula I contains a lactone ring, a linkage group (X), and an R group.

72. Warner-Lambert claimed the disclosed compounds were "useful as hypocholesterolemic or hypolipidemic agents by virtue of their ability to inhibit the biosynthesis of cholesterol through inhibition" of the HMG-CoA reductase enzyme. For support, the specification detailed the biological activity of three compounds compared to the prior art.

73. Research in the 1980s demonstrated that the open lactone ring forms of statin molecules were highly potent cholesterol synthesis inhibitors and are often more potent than the closed lactone ring forms of the same molecules. Warner-Lambert claimed that the invention contemplated the hydroxyl acids, or structural formula I with an opened lactone ring:

> Also contemplated as falling within the scope of the present invention are the hydroxyl acids, and pharmaceutically acceptable salts thereof, derived from the opening of the lactone ring of the compounds of structural formula I above.

74. Importantly, **Warner-Lambert's patent application specifies and covers a compound in which the R-trans enantiomer is isolated:**

> The compounds of structural formula I above possess two

> asymmetric carbon centers, one at the 4-hydroxy position of the pyran-2-one ring, and the other at the 6-position of the pyran-2-one ring where the alkylpyrrole group is attached. This asymmetry gives rise to **four possible isomers,** two of which are the R-cis-and S-cis-isomers and the other two of which are the R-trans- and S-trans-isomers. **This invention contemplates only the transform** of the compounds of formula I above.

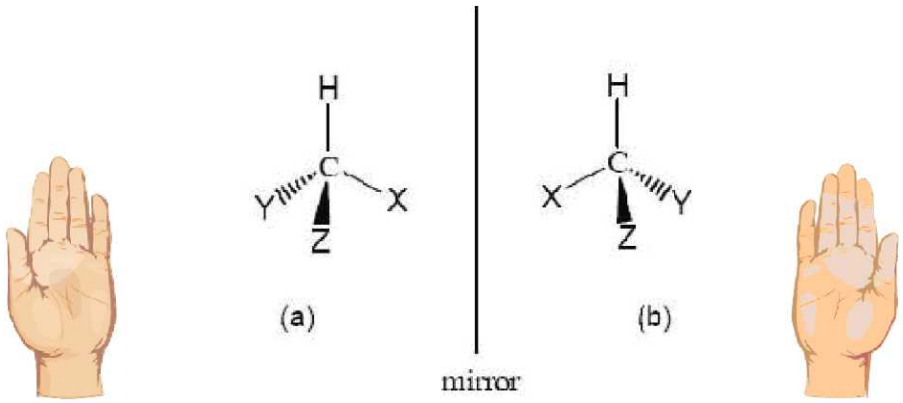
(Emphases added.)

2. The Chemistry of Enantiomers

75. To understand how the '893 Patent covered compounds which included the isolated "R-trans enantiomer," and that it included the R-trans enantiomer in calcium form, some background of the chemistry of enantiomers is helpful.

76. *Enantiomers* are isomers that are mirror images of each other but cannot be superimposed. For example, a person's left hand and right hand are non-superimposable mirror images of each other. Images (a) and (b) in Figure 5 below are enantiomers (where the carbon atom is the chiral center around which a compound's structure is built).

Figure 5: Example of Pair of Enantiomers



77. Pairs of enantiomers share many chemical and physical properties, such as identical melting points, solubility, and colors. Other properties, such as biological properties, may differ.

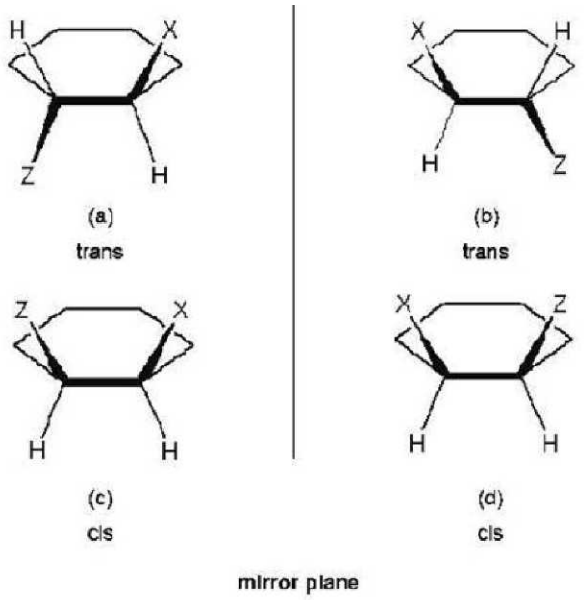
78. Enzymes, including HMG-CoA reductase, typically display a preference for interacting with one enantiomer over the other. It is common for one enantiomer of an enantiomeric pair to have all or most of the biological activity when interacting with an enzyme, while the other has little or no biological activity.

79. Enantiomers can be distinguished from one another by their effect on the rotation of polarized light, and are said to be *optically active.* Enantiomers reflect polarized light in either a clockwise direction (right, denoted with a "+") or a counter-clockwise direction (left, denoted with a "-"). An unequal mixture of two enantiomers is optically active; the degree of optical rotation reflects the percentage of each enantiomer in the mixture. A mixture of equal amounts of two opposite enantiomers is called a *racemic mixture* or *racemate*. A racemic mixture is not optically active because the optical rotations of the enantiomers cancel each other.

80. To differentiate enantiomers in written form, each enantiomer is assigned a configuration, *i.e.*, the arrangement of atoms that characterizes a particular enantiomer and represents the molecule's three-dimensional structure. Configuration designations are determined by priority rules that rank the atoms or substituent group of atoms that are attached to the chiral center. If the priority proceeds in a clockwise direction, the enantiomer has an 'R' (right) configuration; if the arrangement is counter-clockwise, the enantiomer has an 'S' (left) configuration.

81. In addition to R/S and +/- configurations, a molecule's configuration can also reference the location of the substituent atoms or groups of atoms relative to each other. An arrangement where both the major substituents lie on the same side of the plane of reference is called a *cis* arrangement. An arrangement where the major substituents appear on the opposite sides of the plane is called a *trans* arrangement. The placement of X and Z in the figure below demonstrates these cis and trans arrangements.

Figure 6: Examples of Cis and Trans Arrangements



82. The lactone rings found in statins have two chiral centers, one at the carbon with the hydroxyl group and the other at the carbon attached to the linker. Rings containing two chiral centers give rise to four possible isomers -- the R-cis-isomer, the S-cis-isomer, the R-trans -- isomer, and the S-trans-isomer -- and two enantiomeric pairs -- R-cis-isomer & S-cis-isomer and R-trans-isomer & S-trans-isomer.

83. Research at the time demonstrated that the preferred configuration for the lactone ring in a statin -- the configuration offering the highest level of cholesterol inhibition -- was the R-trans configuration.[7] Both mevastatin and lovastatin have lactones in the R-trans configuration. In the case of HMG-CoA reductase inhibitors, the R-trans enantiomer appeared to be the active enantiomer and the S-trans enantiomer the inactive one.

84. Consistent with this conventional thinking, Warner-Lambert's application for the '893 Patent contemplated the trans-form of the compounds in structural Formula I, *i.e.*, racemic or enantiomeric forms of structural formula I. Furthermore, the application contemplated atorvastatin in variety of formulations, including calcium salts.

3. The PTO Issued the Original Lipitor Patent

85. On July 21, 1987, the PTO issued the '893 Original Lipitor Patent.[8] The '893 Patent was assigned to Warner-Lambert. In the absence of an extension, the Original Lipitor Patent would have expired on May 30, 2006, twenty years from the date of the first application. Later extensions lengthened the period of patent protection until March 24, 2010. (The extensions are discussed below.)

86. The '893 Patent envisioned formulations containing only the R-trans or S-trans enantiomers of compounds of structural formula I. The '893 Patent also recognized that these compounds could be in acid or salt form. While the '893 Patent covered multiple formulations of compounds having structural formula I, Warner-Lambert focused on developing and

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[7] See, e.g., Alberts, A. *et al., J. Proc. Natl. Acad. Sci. USA* 1980, 77:3957; Stokker, G.E., *et al., J. Med. Chem.* 1985, 28:347-358; Stokker, G.E. et al., *J. Med. Chem*, 1986, 29: 849-852.

[8] The PTO conducted two separate reexamination proceedings with respect to the '893 Patent. Neither of these reissue proceedings is relevant to Plaintiffs' claims in this matter.

commercializing the R-trans enantiomer of structural formula I in calcium salt form, which it called "atorvastatin". The '893 Patent thus covered atorvastatin.

C. Warner-Lambert Obtained a Follow-On Enantiomer Patent By Fraud[9]

87. Although the '893 Patent was expected to provide Warner-Lambert with many years of patent protection and many years of exclusive sales of Lipitor, Warner-Lambert nevertheless sought to extend *even further* the period for exclusive sales for its new statin.

88. In doing so, Warner-Lambert faced certain realities. Warner-Lambert knew that the R-trans enantiomer was the active enantiomer responsible for atorvastatin's ability to inhibit cholesterol. Warner-Lambert also knew that the PTO would reject an application to patent an enantiomer covered by the '893 Patent; after all, such an "invention" would be either anticipated (that is, already covered) by the '893 Patent, or obvious in light of the '893 Patent. Thus, Warner-Lambert knew it could obtain a follow-on patent specifically for the R-trans enantiomer only if it could convince the PTO that the isolated R-trans enantiomer had a surprising or unexpected characteristic.

89. Senior management at Warner-Lambert instructed the Warner-Lambert researchers to review the **pre-existing** biological data for the R-trans enantiomer to find data that supported both (i) a claim that the activity of the isolated R-trans enantiomer was surprising and (ii) the patentability of the isolated R-trans enantiomer. Regarding the instructions from these senior Warner-Lambert officials, Dr. Roth, the inventor, testified:

> [I]f I found something surprising I would provide that. And what I

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[9] Many of the facts recounted in this section have come to light during international patent litigation. *See, e.g., Ranbaxy Australia Pty Ltd. v. Warner-Lambert Company LLC*(Appeal), 2008 FCAFC 82 (May 28, 2008); *Pfizer Canada Inc. v. Ranbaxy Labs. Ltd.*, 2007 FC 91 (January 25, 2007); *Ranbaxy Australia Pty Ltd. v. Warner-Lambert Company LLC*, 2006 FCA 1787 (December 20, 2006); *Pfizer Canada Inc. v. Novopharm Ltd.*, 2006 FC 1471 (Dec. 17, 2006).

> did do was I provided that information to the patent attorney for Warner-Lambert and asked if that was sufficient, and it was and so that was the data that was used.

90. Of course, when senior Warner-Lambert management sent Dr. Roth back to the old laboratory notebooks to "find" something surprising, there was already a wealth of knowledge about statins and the formulation of isolated R-trans enantiomers. The state of the art about statin formulations sets a context for the later fraud.

1. Knowledge of One Skilled in the Art of Statins in 1989

91. Statins are in the field of synthetic organic chemistry as it applies to discovery of compounds suitable for use as drugs directed to the regulation of the cholesterol biosynthetic pathway and HMG-CoA reductase inhibitors. One of ordinary skill in the art of statins would have at least a bachelor's degree in organic or medicinal chemistry; a general working knowledge of statins; several years of bench work in organic molecule synthesis; some general knowledge of biochemistry and enzymology; knowledge of stereochemistry of pharmaceutically active compounds; and knowledge of resolving racemates.

92. In 1989, one skilled in the art would be knowledgeable about the biological pathway for the synthesis of cholesterol, including that HMG-CoA reductase is the rate limiting enzyme in the biological pathway for cholesterol produced in an organism. One skilled in the art would also know that statins were potent inhibitors of HMG-CoA reductase and that the scientific literature had described *in vitro* assays as methods for testing a compound's ability to inhibit cholesterol synthesis.

93. One skilled in the art would be aware that mevastatin (compactin) is a natural HMG-CoA reductase inhibitor that exists as a single enantiomer. One would also be aware that lovastatin (mevinolin), another potent inhibitor of HMG-CoA reductase, had been isolated and was

structurally very similar to compactin. One would know that both mevastatin and lovastatin have lactones in the R-trans configuration.

94. One skilled in the art would also be aware that pravastatin (1979), simvastatin (1981), and fluvastatin (mid-1980s) were developed/isolated prior to 1989.

95. One skilled in the art would understand that pharmaceutical research into improved inhibitors of HMG-CoA was focused on analogues of known statins. One would be aware that researchers were retaining the lactone ring while investigating substitutions on the remainder of the molecule.

96. One skilled in the art would know that the ring-opened form of the upper lactone portion of the previously discovered statins is significantly more active in inhibiting HMG-CoA reductase than the lactone (closed-ring) form.

97. One skilled in the art would be knowledgeable that HMG-CoA reductase inhibitors are enantiomeric, and one enantiomer is likely to be more active than the other. One would know that the biological activity of a racemate in a biological system can be quite different from that of a single enantiomer, and one enantiomer is approximately twice as active as the racemate in terms of its operation in a target biological system (i.e., because one enantiomer is “active” and the other “inactive,” the active enantiomer is about twice as active as the racemic mixture containing equal amounts of both the active and inactive enantiomers). One would also know that it is desirable to separate and remove the less active enantiomer.

98. One skilled in the art would know that in the case of HMG-CoA reductase inhibitors, the R enantiomer was very likely the active enantiomer and, conversely, the S enantiomer was very likely the inactive enantiomer. One would know that these expected activities could be definitively confirmed by isolating and testing the activity of the enantiomers.

99. One skilled in the art would understand that racemic mixtures can be separated or resolved into the individual enantiomers by well-known methods of separation or resolution. Similarly, one would be aware that single enantiomers can be isolated by chiral or achiral synthesis.

100. One skilled in the art would be knowledgeable that it was common practice among medicinal chemists and others working in the drug discovery field in 1989 to use a single structural formula to represent both enantiomers individually as well as mixtures of enantiomers. One would be similarly aware that whether a diagram depicting the structural form of a molecule or class of molecules shows a particular stereochemistry configuration (whether absolute or relative) depends on the context in which the diagram appears. One would know that if a diagram of a single enantiomer was intended to depict a racemate, to the exclusion of the enantiomer, it was possible to add an additional descriptor, such as (+/-), RS, or ('rac'), which would make it clear that the structure represented only a racemate.

101. One skilled in the art, given the '893 Original Lipitor Patent, would have known that compounds in the structural formula I were racemic, that there were a discreet number of pure optically active isomers possible from the structural formula, and that there were known methods for dissolving the racemic mixture into the pure optically active isomers.

2. The Application: Warner-Lambert Fraudulently Claimed the R-Trans Enantiomer is Ten Times More Active than the Racemate

102. On July 21, 1989, Warner-Lambert submitted a patent application for the optically pure active R-trans isomer, *i.e.*, for the R-trans form of the ring-opened acid described in the '893 Patent: [R-(R*R*)]-2-(4-fluorophenyl)-P,5-dihydroxy-5-(1-methylethyl)-3-phenyl-4-

[phenylamino)carbonyl]-1H-pyrrole-1-heptanoic acid and "its lactone form and salts thereof."[10] Dr. Roth was the applicant. The patent application was signed and submitted by a Warner-Lambert employee. The application eventually led (albeit by fraud) to the issuance of the '995 Enantiomer Patent.

103. The application for the enantiomer patent was prosecuted from 1989 to 1993. The back and forth between Warner-Lambert and the PTO over those years demonstrates the materiality of Warner-Lambert's misrepresentations.

104. In the application, Warner-Lambert asserted: "It is now **unexpectedly found** that the enantiomer having the R form of [a] ring-opened acid [described in the '893 Patent] … **provides surprising inhibition** of the biosynthesis of cholesterol." Warner-Lambert further asserted that "an ordinarily skilled artisan may not predict the **unexpected and surprising inhibition** of cholesterol biosynthesis of the present invention in view of [prior] disclosures." In support of this contention, Warner-Lambert presented only one piece of evidence: a short table stating that Warner-Lambert's Cholesterol Synthesis Inhibition ("CSI") assay data demonstrates the R-trans enantiomer is **one hundred-times more active** than the S-trans enantiomer, and **ten-times more active** than the racemate, in inhibiting the synthesis of cholesterol *in vitro* ("CSI Table"):

[10] As part of the application, Dr. Roth provided a declaration pursuant to 37 C.F.R. § 1.63. In the declaration, Dr. Roth appointed Warner-Lambert's patent attorneys as his attorneys/agents and authorized them to prosecute the application. He further directed the PTO that all correspondence related to the patent application be sent to Warner-Lambert attorney Joan Thierstein. The application itself was signed and submitted by a Warner-Lambert employee, Elizabeth M. Anderson.

is now also incorporated by reference therefor. The CSI data of the compound I, its enantiomer the compound II and the racemate of these two compounds are as follows:

Compound	IC_{50} (micromoles/liter)
[R-(R*R*)] isomer	0.0044
[S-(R*R*)] isomer	0.44
Racemate	0.045

Accordingly, the present invention is the pharmaceutical composition prepared from the compound of the formula I or II or pharmaceutically acceptable salts thereof.

105. Warner-Lambert claimed the "present invention" -- the R-trans enantiomer -- was ten times more powerful than its racemate in inhibiting cholesterol synthesis based on the data presented in the CSI table.

106. A "CSI assay" measures the ability of a compound to inhibit cholesterol biosynthesis along the entire cholesterol biosynthesis pathway and is one of the most commonly used methods to test a compound's ability to inhibit the synthesis of cholesterol *in vitro.* The CSI test does not identify the specific step in the cholesterol biosynthetic pathway that is being inhibited, nor is it specific to HMG-CoA reductase. The results of a CSI assay are reported as an IC_{50} value, the concentration of a test compound that produces 50% inhibition in the conversion of cholesterol-[^{14}C] acetate to radioactive cholesterol.[11]

107. One skilled in the art of statins in 1989 would have expected the active R-trans enantiomer to be about twice as active as the racemate in inhibiting cholesterol synthesis. Activity of one enantiomer that is more than ten times that of the racemate would have been "unexpected" and "surprising" if the findings were based on true or accurate data. In truth, they were not.

[11] Two other commonly used methods of measuring a compound's inhibition of cholesterol are the *in vivo* Acute Inhibition of Cholesterol Synthesis ("AICS") assay and the *in vitro* CoA Reductase Inhibition ("COR") assay. The COR assay measures a compound's ability to inhibit HMG-CoA reductase specifically and is typically used to confirm that the activity seen in the CSI assay is attributable to inhibition of the desired target: HMG-CoA reductase.

a. The CSI Table Was Misleading and Affirmatively False

108. Warner-Lambert's biological data -- the CSI Table -- was both affirmatively false and intentionally presented in a misleading manner. The CSI Table purported to present reliable scientific data. It did not. In truth, it contained limited data cherry-picked from multiple flawed tests conducted over several years using different formulations of various atorvastatin salts. And the biological data was false: reliable data actually shows that the R-trans enantiomer is, as expected, only about two times more active than the racemic mixture -- not the ten-fold increase Warner-Lambert claimed.

(1) The CSI Table Was False and Misleading

109. The CSI Table was false and misleading because it did not present reliable data. CSI assays can vary greatly from one test to another. Warner-Lambert's CSI Table did not disclose the source of its data, and failed to indicate the number of CSI assays performed, the degree of variation in the test results, what molecules were tested, the time period over which the assays were run, or whether the results presented were drawn from multiple tests. Given this lack of specification, a skilled addressee would conclude that Warner-Lambert would not have included the CSI Table in the specification in such an unqualified way unless the data had been confirmed by a number of repeat assays, and that it fairly depicted all such appropriate data.

110. While not apparent from the face of the specification, Warner-Lambert asserted in subsequent litigation that the CSI Table was created by averaging the results of all of the available CSI screens. This was not true. Warner-Lambert ran a number of CSI assays prior to applying for the '893 Patent -- over a multi-year period and on various salt formations -- as it tested the R-trans enantiomer of structural formula I. The results fluctuated wildly. Warner-Lambert cherry-picked

from among the results in order to generate a table that purportedly supported the claim of "surprising activity."

111. For example, the CSI Table combined results from a number of different CSI assays and compared them to a separate CSI assay. But the standard in the 1980s for giving numbers of the kind found in the CSI Table was to conduct repeated head-to-head tests; Dr. Roth himself acknowledged that head-to-head testing provides the best way to compare quantitative differences in activity. However, the data presented to the PTO for the R-trans enantiomer and S-trans enantiomer were taken from a single run of the same experiment: CSI 120. And in bizarre contrast, the data collected for the racemate represents an "average" of five separate assays: CSI 92, CSI 93, CSI 95, CSI 102, and one of three recorded values from CSI 118.

112. Second, taking an average across different days and experiments is not appropriate. The five "averaged" assays were conducted over a three-year period from July 1985 through October 1988. When taken as a whole, the results of these five experiments reported for the racemate are so variable that they cannot be averaged together with any reliability and do not provide a scientifically meaningful result.

113. Third, it is also inconsistent with accepted pharmaco-chemistry to "average" the results of CSI values derived from both opened lactones and separately synthesized sodium salts. Four of the assays reflected in the racemate data in the CSI Table started with the lactone (unopened) form of racemic atorvastatin and were treated with sodium hydroxide to open the lactone ring. One of the assays started with an opened formulation of the racemic atorvastatin, the sodium salt.

114. Moreover, the table does not even constitute an average of all the measurements available to Warner-Lambert. Warner-Lambert cherry-picked the measurements that it averaged,

omitting the results of CSI 107, CSI 111, CSI 112, CSI 119, CSI 120, CSI 122, CSI 123, CSI 124, CSI 136, and CSI 138.

115. Depending on which assays were included or excluded, the CSI Table could have, and would have, reported very different results. For example, Dr. Roth acknowledged that had the results of CSI 107 been included in his "average," there would be no surprising or unexpected result. Had CSI 107 been included, the CSI Table would only show, as expected, a two-fold increase in the activity of the R-trans enantiomer compared to the racemate. Dr. Roth claimed that he did not include CSI 107 because he believed that the tested compounds were not enantiomerically pure; yet, he included the results of CSI 120, which suffered from a not substantially different level of contamination.

116. Similarly, the CSI Table would have shown only the expected two-fold increase had Warner-Lambert excluded the results of CSI 118 from the "average."

(2) Warner-Lambert's Representations that the R-Trans Enantiomer Was Ten Times More Active than the Racemate Were Affirmatively False and Misleading

117. Warner-Lambert's claim of ten-fold greater activity of the R-trans enantiomer compared to the racemate was false. The only consistent test results show that the R-trans enantiomer was, as expected, only about twice as active as the racemic mixture.

118. Warner-Lambert, including Thierstein and Roth, did not tell the PTO that they possessed data that expressly contradicted representations in its patent specification. In addition to CSI assays, Warner-Lambert assessed the activity of the R-trans enantiomer, S-trans enantiomer, and the racemate through the *in vivo* AICS assay. The AICS assay -- the only screen to be conducted twice and with consistent results -- showed a two-fold increase in activity of the R-trans enantiomer over the racemate. Warner-Lambert's own research report, dated May 21, 1989, stated

that the R-trans enantiomer "was approximately *twofold* more active at inhibiting cholesterol synthesis acutely *in vivo* compared to the racemic mixture …. *This is to be expected* if 50% of the racemic salt is the inactive isomer."

119. Warner-Lambert did not submit the AICS data to the PTO.

120. Dr. Roth and Warner-Lambert knew that the PTO would read the CSI Table as fairly reflecting all of the appropriate CSI data available to Warner-Lambert for the relevant compounds and that the data as a whole provided reasonable grounds for the findings set forth in the CSI Table. Dr. Roth and Warner-Lambert intended the CSI Table to be read as suggesting a ten-fold increase in activity and therefore supporting patentability.

121. Dr. Roth and Warner-Lambert also knew that the CSI data did *not* provide any "surprising" results. After all, Warner-Lambert scientists, including Dr. Roth, had conducted the various CSI assays over a period of more than three years. Certainly, if the assays had disclosed anything surprising -- and certainly something as surprising as an isolated R-trans enantiomer with ten-fold biological activity over the racemic mixture -- that would have been learned, in real time, as the tests unfolded. But they did not. Instead, it was only after senior Warner-Lambert managers (not the scientists) instructed Dr. Roth to go back and "find" something in the data, and after a hodge-podge analysis of different tests on different compounds was cobbled together, that the claimed ten-fold biological activity materialized.

122. Furthermore, accepted chemistry in 1989 provided for the controlled testing of any proposed hypothesis, *i.e.*, that there were some "surprising" attributes of the isolated R-trans enantiomer over the racemic mixture. This would have entailed *new* tests in response to senior managements' demand to find something surprising. Instead, the entire direction, dictated by senior Warner-Lambert management, was *not* to conduct acceptable science to support fair and

accurate representations to the PTO. The instructions were simply to go back and gin-up old data to give an impression, albeit false, of some type of "surprising" attribute.

3. The Initial Rejection: The PTO Determined the Claimed Compounds Were Anticipated By the '893 Patent

123. On March 22, 1990, pursuant to 35 U.S.C. § 102(b), the PTO rejected all claims in the initial application as anticipated by the '893 Patent. The PTO determined that the '893 Patent "restrict[ed] the invention to the trans-isomers and... specif[ied] the R*, R* configuration. Thus, the claimed compounds, salts, compositions, and method are considered to be anticipated by [the '893 Patent]." Put simply, the PTO rejected Warner-Lambert's enantiomer patent application because the invention was already covered by the claims in the Original Lipitor Patent.

124. The concepts in patent law of "anticipation" and "non-obviousness" are distinct but related. A proposed invention may be rejected under 35 U.S.C. § 102(b) as being anticipated if each of its elements is disclosed by a previous patent. Alternatively, even if a proposed invention is not identically disclosed or described as set forth in § 102, under 35 U.S.C. § 103 a patent may not issue for obviousness "if the differences between the subject matters sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains[.]" Because the patent examiner had concluded that the '893 Patent anticipated the isolated R-trans enantiomer form of atorvastatin, the examiner did not need to reach the concept of obviousness.

125. In response to this rejection, Warner-Lambert argued against anticipation on the technical grounds that "the presently claimed compounds are for individual enantiomers and therefore differ from the teaching in [the '893 Patent] only to mixtures of enantiomers."

Warner-Lambert argued that the '893 Patent did not specifically identify, and therefore did not technically "anticipate," the R-trans enantiomer:

> In molecules of the kind disclosed in [the '893 Patent], each possible isomer also exists in two forms which depend on a configuration which is expressed in absolute terms relative to the remainder of the molecule. The forms are denoted as an R form and an S form. These two forms are recognized by an ordinarily skilled artisan to be enantiomeric forms each having a specific chirality. In [the '893 Patent] the disclosure is not limited to compounds having such a specific chirality. Thus, each isomer of [the '893 Patent] is a mixture of enantiomers and not the currently claimed individual enantiomers having an R chirality.

126. In response, the PTO examiner again rejected Warner-Lambert's argument that the Original Lipitor Patent did not anticipate the R-trans enantiomer and, on November 7, 1990, issued a final rejection on anticipation grounds. The examiner determined that the '893 Patent described the R-trans enantiomer of atorvastatin:

> Applicant's arguments . . . have been carefully considered, but such are not persuasive. Where a reference discloses a genus or compound of similar structure which are sufficiently limited in number, the reference is deemed to provide description of those compounds just as specifically as if they were identified by name.

The examiner further observed that, to isolate the claimed invention from the compounds disclosed in the '893 Patent, "one merely has to select from the limited possibility of isomers to arrive at the claimed invention, and separate them using conventional techniques."

4. The Renewed Application: Warner-Lambert Submitted the Roth Declaration, Again Falsely Claiming the R-Trans Enantiomer is Ten Times More Active than the Racemate

127. On February 29, 1991, Warner-Lambert filed a request for retroactive extension of time for revival of the application, a preliminary amendment, and a declaration by Dr. Roth ("Roth Declaration"). The declaration again claimed a "surprising" and "unexpected" ten-fold increase in activity. It falsely professed to present seemingly objective evidence of an unexpected

characteristic of the isolated R-trans enantiomer, and Warner-Lambert claimed this characteristic would allow issuance of an R-trans enantiomer patent despite the claimed invention being *prima facie* obvious in light of the '893 Patent. The Roth Declaration simply presented more of the same: affirmatively false and misleading biological data.

a. Warner-Lambert Admitted the R-Trans Enantiomer Is *Prima Facie* Obvious

128. While Warner-Lambert presented technical reasons as to why the proposed R-trans enantiomer patent was not "anticipated" by the Original Lipitor Patent, Warner-Lambert did raise, on its own, the issue of obviousness. Indeed, Warner-Lambert admitted that the R-trans enantiomer was *prima facie* obvious in light of the '893 Patent. In its remarks in support of the renewed patent application, Warner-Lambert directed the examiners' attention to a decision of the U.S. Court of Customs and Patent Appeals, *In re May and Eddy*, 197 USPQ 601, 607 (1978), quoting: "As recognized in *In re Williams*, 36 CCPA 756, 171 F.2d 319, 80 USPQ 150 (1948), the novelty of an optical isomer is not negated by the prior art disclosure of its racemate."[12] "Clearly," Warner-Lambert asserted, "this case law is applicable here."

129. In *May*, the applicant **conceded prima facie obviousness,** but submitted "rebuttal evidence" in the form of four declarations that it was "unexpected" that the compounds in question did not exhibit the addictive qualities of most opiates. The PTO refused to consider the rebuttal evidence, but the U.S. Court of Customs and Patent Appeals overturned the refusal and made its own findings as to whether (i) the record supports non-addictiveness and (ii) non-addictiveness would have been unexpected to one of ordinary skill in the art. "[B]alancing the *prima facie* case

[12] The facts here are quite distinct from *Williams*. In *Williams*, the court determined that the racemic compound had been disclosed in the prior art, but (in contrast to the situation here) the fact that the compound was racemic had not been disclosed prior to the priority date.

of obviousness made out by the PTO against appellants' objective evidence of nonobviousness," the Court concluded, "the subject matter of claims 11-13 would not have been obvious to one of ordinary skill in the art." *May*, therefore, stands for the proposition that when a claimed invention is *prima facie* obvious, an applicant may provide declarations identifying objective evidence of a surprising characteristic to overcome an obviousness rejection.

130. For the enantiomer application, Warner-Lambert purported to do just that. In the remarks, Warner-Lambert stated:

> Following the *Williams* case Applicant also now provides by a declaration a comparison among each enantiomer and mixture of enantiomers. This comparison is provided to overcome the Roth reference [that is, the reference in the Original Lipitor '893 Patent] of the present rejection to facilitate a finding of patentability and moving the prosecution toward resolution of pertinent issues. In other words, **although Examiner has not included a rejection under 35 U.S.C. 103 [for obviousness] Applicants are including a rebuttal of such rejection to comply with the *Williams* case law.**

Warner-Lambert further described the declaration as "provid[ing] the data as set out in the present application in a manner to provide patentability to the application,"[13] and stated, "in other words, **the declaration is submitted to provide evidence of patentability** to the instant invention."

b. The Roth Declaration Was Affirmatively False and Misleading

131. Warner-Lambert submitted the Roth Declaration in an effort to overcome the otherwise inevitable rejection on obviousness grounds. The Roth Declaration stated "the antihypercholesterolemia properties of ["R-enantiomer," or "Compound I"] and ["S-enantiomer," or "Compound II"] and mixtures thereof are assessed using essentially the CSI screen that is disclosed in [the '893 Patent]." The declaration further claimed that the R-

[13] Warner-Lambert thus at least tacitly acknowledged that the CSI Table previously submitted in the patent specification is not sufficient to provide patentability.

trans enantiomer has "activity greater than **fifty-fold more** than that of Compound II and which indicates activity **at least ten-fold more** than that of the racemate," and included the following table:

8. THAT, in said assessment, the datum from the Compound I, the datum from its enantiomer the Compound II and the datum from the racemate of the two compounds I and II are as follows:

	Compound	IC_{50} (micromoles/liter)
I	[R-(R*R*)] isomer	0.025
II	[S-(R*R*)] isomer	>1.00
	Racemate	0.26

9. THAT, the data demonstrate that the Compound I provides an IC_{50} which indicates activity greater than fifty-fold more than that of Compound II and which indicates activity at least ten-fold more than that of the racemate;

132. The Roth Declaration gave the impression that all appropriate, reasonably available information regarding CSI assay data was represented in the declaration when it described "the datum from the compound I" and "the datum from the racemate" of that compound. The declaration further claimed that "the differences in the data . . . among Compounds I, II and racemate shows the activity of Compound I is **surprising and unexpected** because if the Compound II is accepted as inactive, the activity of the Compound I would be expected to be only twice that of the racemic mixture."[14] The declaration affirmatively and falsely stated that the data "indicates activity at least ten-fold more than that of the racemate."

[14] Dr. Roth's declaration concluded with a paragraph stating, in part, "these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both. . . and that such willful false statements may jeopardize the validity of the above identified US patent application. . . . or any patent issuing thereon."

133. The Roth Declaration, like the CSI Table, purported to present reliable scientific data but did not disclose the source of that data.[15] Given this lack of specification, a skilled artisan would conclude that Warner-Lambert would not have included the CSI Table in the specification in such an unqualified way unless the data had been confirmed by a number of repeat assays. In fact, the Roth Declaration presented unreliable data from a single, deeply flawed screen -- CSI 118. The declaration was false and misleading.

134. CSI 118 used all three forms of calcium salt in a single head-to-head assay. There is no indication that it was ever re-run to confirm its outcome.[16] The test results are unusable for a number of reasons.

135. First, in order to obtain accurate IC50 values, the concentration of the test solutions must be known prior to testing. But Warner-Lambert did not determine the concentration of its test solutions prior to conducting the CSI 118 test. Without accurate information about the concentration of the solutions used in the CSI 118 test, the IC_{50} values obtained in CSI 118 cannot be used to demonstrate a ten-fold increase in activity of the R-trans enantiomer over the racemate.

136. Second, Warner-Lambert's own lab books show that the compounds in CSI 118 did not dissolve completely in the stock solution. Using non-homogeneous suspensions can result in variations in the concentrations of the compound in the assay solution leading to wide variation in the results obtained. Given this limitation, the most that the CSI 118 results can be said to

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[15] The renewed patent specification also contains a chart (the "CSI Chart") showing ten times greater activity of the R-trans enantiomer than the corresponding racemate. The information contained in this chart is identical to that presented in the original application.

[16] Dr. Roth admitted that he did not conduct any additional tests to confirm that the biological data presented in the patent was in fact correct: "it is true that [the biological data that was included in the patent] went out without any subsequent tests being asked for by me to repeat that data."

determine is whether a compound has **any** activity, not whether a compound has a two-fold, three-fold, or ten-fold increase in activity over another compound.

137. Third, an acceptable CSI test should record similar results for the racemic sodium salt and the racemic calcium salt. (Dr. Roth has agreed that, in general, the results for the racemic sodium salt and the racemic calcium salt should be equivalent or similar.) Yet, in CSI 118, the results of the racemic sodium salt and racemic calcium salt were vastly different, showing as much as a twenty-five-fold difference. The difference was so great that the IC50 value for the R-trans enantiomer calcium salt showed far less potency than the racemic sodium salt -- that is, the R-trans enantiomer of the calcium salt was less active than the racemate of the sodium salt. This difference should have been a red flag that something was wrong with the screen, likely a problem related to the difficulty with solubility of the compounds.

138. Finally, the claim in the Roth Declaration of ten-fold greater activity is also affirmatively false because the activity of the isolated R-trans enantiomer is not in fact ten times greater than the racemate. Had Warner-Lambert employed an acceptable scientific testing process, the data would have revealed the R-trans enantiomer had at best a two-fold advantage over the racemate, an advantage that would have been expected, not “unexpected” or “surprising.”

139. Dr. Roth and Warner-Lambert were aware of the numerous problems with CSI 118 identified above and knew that the results of CSI 118 were not scientifically sound. Yet, in the face of radically different values for the sodium and calcium salts, solubility problems, unknown solution concentrations, and results that showed the racemate of one salt was more potent than the R-trans enantiomer of another salt, they used this questionable and unreliable data to support the false claim that the isolated R-trans enantiomer has ten times greater inhibition of cholesterol synthesis than the racemate, and specifically claimed this as “a surprising level of activity” which,

in turn, supported patentability. Dr. Roth has admitted under oath that he submitted CSI data for the purpose of demonstrating "a surprising level of activity" which therefore supported patentability:

> Q. So [the biological data] was put in to demonstrate this surprising level of activity for the purpose of obtaining a patent, was it not?
>
> A. [Dr. Roth:] Yes, I guess you would say that that would be true. I mean, the data supported a surprising level of activity, which we thought would be novel and surprising and therefore would support patentability.

140. Warner-Lambert knew that the PTO would read the Roth Declaration as fairly reflecting all of the appropriate CSI data available to the Pfizer Defendants for the relevant compounds and that the data as a whole provided reasonable grounds for the findings set forth in the Roth Declaration. Dr. Roth and Warner-Lambert intended that the Roth Declaration should be read as suggesting a ten-fold increase in activity and therefore supporting patentability.

5. The Final Rejection: The PTO Determined the R-Trans Enantiomer Was Anticipated

141. On September 16, 1991, the PTO examiner issued a final rejection of the follow-on patent application, rejecting all claims under 35 U.S.C. § 102(b) as being anticipated by the '893 Patent for the reasons set forth in the two rejections issued in 1990.

6. The Appeal: the PTO Determined the R-Trans Enantiomer Was Prima Facie Obvious

142. On January 15, 1992, Warner-Lambert appealed the examiner's rejection to the Board of Appeals, claiming "[t]he R isomer as claimed appears to be at least **100 times more active than its corresponding S isomer** and **more than 10 times more active than the mixture.** Under ordinary circumstances one would have expected only a two-fold difference between the particular R isomer and the mixture." Warner-Lambert went further, stating "the present invention describes

the particular R isomer which is found to have **greater than 10 times the activity** of the compound described in the prior art reference, namely, the racemic mixture," and "the compound of the present invention … does not produce substantially the same result since it has **greater than 10 times the activity** than the reference compound," and "the R isomer is the most desired and the most **surprisingly active** isomer of the two possibilities if one is to select from the trans compounds[.]"

143. Acknowledging that the isolated R-trans enantiomer is *prima facie* obvious over the '893 Patent, Warner-Lambert argued that the obviousness is overcome by the surprising and unexpected activity claimed in the Roth Declaration: "The examiner's rejection is erroneous as a matter of law by applying the facts of the present case to the wrong law. The issue here is whether an optical isomer is novel over its prior disclosed racemic mixture. The law as state[d] in *May and Eddy* affirming *In re Williams* says yes."

144. On March 24, 1992, the examiner filed an answer to Warner-Lambert's appeal. The examiner alleged no new grounds for denial of the application, but reiterated the previously disclosed grounds, stating, "even if a preferred isomer were not disclosed [by the '893 Patent], one skilled in the art expects one of the individual isomers to be more active than the other since this, too, is knowledge contemporary in the art."

145. On October 19, 1992, the Board of Appeals overturned the Examiner's rejection **for anticipation** of the application, concluding that the '893 Patent:

> at best, only describes the trans racemate containing the R-trans and the S-trans isomers in admixture. Nowhere does [the '893 Patent] state or suggest which optical isomer is preferred and, moreover, does not specifically mention how one skilled in the art could make the pure optical isomer separately. In view of the above, we are unable to subscribe to the examiner's contention that the ['893 Patent] anticipates the claimed subject matter.

146. However, the Board recommended to the examiner that upon remand the patent should be rejected on the basis of **obviousness:**

> Upon further prosecution of this application before the examiner, we recommend that the examiner analyze the claimed subject matter under the provisions of § 103 of 35 USC. **An obviousness rejection of claims directed to an optically pure isomer appears to be in order when, as here, (1) the product of the prior art is known to be racemic and (2) where methods for resolving the racemic mixture into the pure optically active isomers are known to those skill[ed] in the art.**

7. The '995 Patent Issues: PTO Relied on Biological Data to Overcome Obviousness

147. On March 16, 1993, apparently without any further formal proceedings or briefing, the PTO issued a Notice of Allowability for the follow-on, isolated R-trans enantiomer patent application. The '995 Patent issued on December 28, 1993.

148. Warner-Lambert had presented the results of CSI screens in both the '995 Patent specification and the Roth Declaration to support the contention that the R-trans enantiomer is surprisingly and unexpectedly **ten times more active than the racemate** and therefore not obvious in light of the '893 Patent. Warner-Lambert made this representation in the original application, the Roth Declaration, the appeal to the PTO, and the final patent specification. This is the only "surprising" activity of the isolated R-trans enantiomer that was ever discussed in the '995 Patent application, and the sole reason Warner-Lambert overcame an obviousness rejection.

149. The PTO relied on the Roth Declaration and the CSI Table to find that the R-trans enantiomer was not obvious in light of the '893 Patent. The Board of Appeals explicitly (i) directed the examiner to re-evaluate the application for obviousness, and (ii) stated that an obviousness rejection appeared to be appropriate. The examiner did precisely that. The examiner relied on Warner-Lambert's claim of "surprising" and "unexpected" activity and determined that

the charts presented in support of that claim (both in the patent specification itself and the Roth Declaration) were sufficient to overcome a rejection on obviousness grounds. The only "surprising" or "unexpected" characteristic of the isolated R-trans enantiomer Warner-Lambert claimed was the ten-fold increase in activity compared to the racemic mixture. The only data presented in support of those claims were contained in the patent specification (the CSI Table) and Roth Declaration.

150. The inclusion of particular language and data in the patent specification itself confirms that the PTO relied on both the claim of surprising and unexpected activity and the data submitted in support of that claim. The specification states, "[i]t is now unexpectedly found that the enantiomer having the R form of [a] ring-opened acid [described in the '893 Patent], . . .that is [R-(R*R*)]-2-(4-fluorophenyl)-P,5-dihydroxy-5-(1-methylethyl)-3-phenyl-4-[phenylamino)carbonyl]-1H-pyrrole-1-heptanoic acid, provides surprising inhibition of the biosynthesis of cholesterol." The specification further states "an ordinarily skilled artisan may not predict the unexpected and surprising inhibition of cholesterol biosynthesis of the present invention in view of [prior] disclosures."

151. But for Warner-Lambert's fraud, the '995 Patent would never have issued.

D. Warner-Lambert Intended to Deceive the PTO

152. Warner-Lambert's false claims and data were made and provided to the PTO with the specific intent that the PTO rely on those claims in order to issue a follow-on patent, and with knowledge they were false and misleading. Dr. Roth and Warner-Lambert knew that the PTO would read the CSI table and the Roth Declaration as a representation that the results in the table fairly reflected all of the available scientifically reliable CSI data for the relevant compounds and that the data as a whole provided reasonable grounds for the findings set forth in the CSI Table.

Dr. Roth and Warner-Lambert intended that the CSI table and the Roth Declaration should be read as suggesting a ten-fold increase in activity and therefore supporting patentability.

1. Warner-Lambert Manipulated the Existing Biological Data to Show a Ten -Fold Increase in Activity and the Pfizer Defendants Intentionally Presented False Information

153. Warner-Lambert manipulated the existing biologic data in order to show a ten-fold increase in activity. It did so with specific intent to deceive the PTO.

154. Warner-Lambert acknowledged that head-to-head testing provides the best way to compare quantitative differences in activity, yet it did not present such head-to-head data in support of its claim of ten-fold activity of the R-isomer over then racemate. Instead, Warner-Lambert selected results from various tests conducted on different days, using different salts, and suffering from various flaws and presented these cooked-up results in the CSI Table included in the patent specification. Such an extreme departure from accepted chemistry practice -- by a company fully aware of what accepted chemistry practice would have required -- shows knowledge of falsity and specific intent to deceive.

155. Warner-Lambert acknowledged that had the results of CSI 107 been included in this "average," there would be no surprising or unexpected result. Warner-Lambert claimed that it did not include CSI 107 because it believed that the compounds it tested were not enantiomerically pure; yet, it included the results of CSI 120, which suffered from a not substantially different level of contamination. Such an extreme departure from accepted chemistry practice shows knowledge of falsity and specific intent to deceive.

156. Warner-Lambert claimed that it did not provide the data from CSI 119 to the PTO because CSI 119 was not a head-to-head comparison, and it claimed it believed that it was inappropriate to compare individual data points from different experiments. Yet Warner-Lambert

used different data points from multiple experiments to generate the data contained in the CSI Table. Such an extreme departure from accepted chemistry practice shows knowledge of falsity and specific intent to deceive.

157. Warner-Lambert included one of the three results from CSI 118 in the CSI Table in order to show an alleged ten-fold increase in activity. The sodium salt prepared by opening the racemic lactone in CSI 92, 93, 95, and 102 should have given substantially identical, or at least very similar, values to the racemic sodium salt that was separately prepared in CSI 118. Yet, the results for the racemic sodium salt in CSI 118 differ from the results of the four lactone CSI tests by a factor of ten. Such an extreme departure from accepted chemistry practice shows knowledge of falsity and specific intent to deceive.

158. In CSI 118, the results of the racemic sodium salt and racemic calcium salt are vastly different, showing as much as a twenty-five-fold difference. The difference was so great, that the IC50 value for the R-trans enantiomer calcium salt showed far less potency than the racemic sodium salt -- that is, the R-trans enantiomer of the calcium salt was less active than the racemate of the sodium salt. This difference should have been a red flag that something was wrong with the screen, likely a problem related to the difficulty with solubility of the compounds. Instead, Warner-Lambert used this questionable data to support the false claim that R-trans enantiomer has a ten-fold greater inhibition of cholesterol synthesis than the racemate.

159. Warner-Lambert was aware of the numerous problems with CSI 118 identified above and knew that the results of CSI 118 were not scientifically sound. Yet, in the face of radically different values for the sodium and calcium salts, solubility problems, unknown solution concentrations, and results that showed the racemate of one salt was more potent than the R-isomer of another salt, Warner-Lambert used this inconsistent outcome to further substantiate its false

claim that the R-isomer was ten times more active than the racemate in inhibiting cholesterol synthesis.

160. Warner-Lambert's patent attorneys submitted the false and misleading CSI table generated by Dr. Roth and others and the false and misleading Roth Declaration to the PTO in furtherance of a deliberately planned and carefully executed scheme to defraud the PTO to gain approval of the '995 Patent application.

2. Warner-Lambert Admitted the Patent Specification Claims a Surprising Ten-Fold Increase in Activity

161. At numerous points in the prosecution of the '995 Patent, Warner-Lambert and Dr. Roth expressly stated that the activity of the R-trans enantiomer was both surprising and ten-times greater than the activity of the racemic mixture. Nonetheless, in subsequent patent litigation, Dr. Roth and Warner-Lambert shied away from admitting that Warner-Lambert had claimed that the surprising feature of the R-trans enantiomer was a ten-fold increase in activity over the racemate. Warner-Lambert knew that both the CSI table and Roth Declaration presented false information about the activity of the R-trans enantiomer as compared to the S-trans enantiomer and the racemate. To acknowledge in court that the only claimed "surprising" characteristic was in fact false would result in the loss of the '995 Patent and/or its foreign counterparts.

162 Dr. Roth's evasive testimony on this topic is illustrative:

> Q: I suggest to you that you either do or do not rely on those figures. If you want to put out a merely qualitative statement that you have surprising activity you can put it in words. If you put it out in figures that suggests that it is a very surprising level of activity, being a 10-fold difference?
>
> A: But I believe the words we used were a surprising level of activity. We didn't say that it was surprising because it was a 10-fold difference. We simply said that it was surprising, the numbers suggest 10-fold. But frankly, again, anything more than twofold would be surprising. We didn't claim 10-fold in the patent. We said it was surprising.

Q: You didn't put a qualification to the numbers that you give in the patent to say "beware of these numbers. We're only really saying that we get a better than two-fold improvement"; no mention of that, was there?

A: What we say is that the compound has surprising activity and then we put data into the patent which supported the surprising level of activity. I don't think that we actually comment on the data except to say that it's surprising. The data is what the data is.

Q: The data on its face quantify that is surprising level of activity, does it not, Dr. Roth?

A: There are numbers given, yes.

Q: So it quantifies that surprising level of activity?

A: What do you mean by that?

Q: Do you know what the meaning of the word "quantifies" is?

A: There are numbers that are given. Again, we don't make any claims; all we say is that it's surprising. The numbers are what the numbers are.

163. Dr. Roth was ultimately forced to concede that the biological data contained in the patent specification purports to show a ten-fold increase in activity, and that it was included in the specification for that reason:

Q: And you wanted those numbers to be taken at face value, did you not?

A: I'm not sure I know what you mean.

Q: What?

A: The data is what the data is. The data was included to support the rising level of activity. What the numbers suggest is that it's something like 10-fold, but we don't state that. We simply -- what we simply do is we say it's surprising.

Q: Isn't it a fair reading of this passage on page 8 that having said it's surprising that you are saying now here is why and you set out figures which show a 10-fold increase and you don't provide any qualification at all to those numbers?

A: That is true. We simply report the data.

164. Dr. Roth acknowledged, "[t]he data is what the data is," "the numbers are what the numbers are," and "the data was included to support the surprising level of activity. What the numbers suggest is that it's something like 10-fold[.]" The numbers show, based on cherry-picked test results, regardless of whether particular words appear in the text of the patent, that the R-trans enantiomer is ten times more active than the racemate. In reality, the R-trans enantiomer is, as expected, only about twice as active as the racemate.

3. Warner-Lambert Intended for the PTO to Rely on the False Data and Claims

165. Dr. Roth admitted under oath that he submitted CSI data for the purpose of supporting a surprising level of activity which therefore supported patentability: "the biological data that was included in the patent I felt demonstrated and supported a surprising level of biological activity."

> Q: So [the biological data] was put in to demonstrate this surprising level of activity for the purpose of obtaining a patent, was it not?
>
> A: Yes, I guess you would say that that would be true. I mean, the data supported a surprising level of activity, which we thought would be novel and surprising and therefore would support patentability.

E. The FDA Approved Lipitor, and the Original Lipitor Patent Provided Years of Patent Protection

166. On June 17, 1996, Warner-Lambert submitted a new drug application under § 505(b) of the FDCA and 21 C.F.R. § 314.50, seeking approval to sell atorvastatin calcium. The formulation developed for FDA approval and commercialization was atorvastatin calcium, *i.e.*, the isolated R-trans enantiomer formulated as a calcium salt. On December 17, 1996, the FDA approved atorvastatin calcium -- brand named "Lipitor" -- for the treatment of hypercholesterolemia and mixed dyslipidemia. The FDA initially approved 10 mg, 20, mg, and 40 mg tablets, adding approval of 80 mg tablets on April 7, 2000.

1. The Orange Book Listings for Lipitor

167. Following approval, under 21 U.S.C. § 355, Warner-Lambert listed both the '893 Patent and the fraudulently-obtained '995 Patent in the FDA Orange Book. When it did so, Warner-Lambert knew that it had procured the '995 Patent by actual fraud on the PTO. By listing both patents in the Orange Book, the Pfizer Defendants forced any generic company seeking approval of an ANDA for generic atorvastatin calcium to file a Paragraph IV certification as to both the '893 and '995 Patents if the generic company wished to enter the market prior to the expiration of both patents. Such a certification would, the Pfizer Defendants knew and intended, trigger the ability of Warner-Lambert to file infringement litigation, which in turn would trigger the statutory Hatch-Waxman 30-month stay of ANDA approval.

168. At the time of FDA approval of Lipitor, the '893 Patent was scheduled to expire on May 30, 2006. The '995 Patent, by contrast, was scheduled to expire on December 28, 2010.

169. The Pfizer Defendants also listed the following patents in the FDA Orange Book as covering Lipitor: 6,126,971 (the "'971 Patent"); 5,686,104 (the "'104 Patent"); and 5,969,156 (the "'156 Patent"). Both the '104 and '971 patents cover particular, and narrow, ways of formulating atorvastatin calcium with various excipients to stabilize the finished pharmaceutical product. These two patents are referred to as the "Unasserted Formulation Patents"; "unasserted" because, despite later efforts by generic companies to enter the market, Pfizer did not assert these two patents against those generic companies (including Ranbaxy). The '156 patent covered the crystalline form of atorvastatin calcium, not the amorphous form. Ranbaxy's product used the amorphous form.

170. As a practical matter, Pfizer knew that potential generic competitors could (and did) design-around these narrow process or formulation patents. No reasonable litigant would have had

any expectation of succeeding against Ranbaxy on a claim alleging infringement of the '971, '104 or '156 patents. Such an infringement claim would have been an objectively baseless sham.

2. The '893 Original Lipitor Patent Protected the Lipitor Franchise for Years

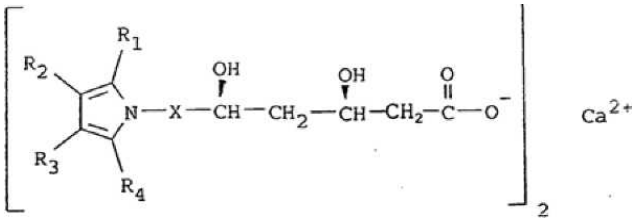
171. Shortly after FDA approval, Warner-Lambert filed with the PTO an application under 35 U.S.C. § 156 for an extension of the term of the '893 Patent. Section 156 provides that the period of patent protection may be extended in order to account for the time lag between the issuance of a patent covering the active ingredient in a new drug, and FDA approval. The time between patent issuance and FDA approval can be significant, and this statute allows the PTO to extend the term of pharmaceutical patents to make up for this lost time on the market.

172. Warner-Lambert asked the PTO to extend the period of market exclusivity granted by the '893 Patent -- not the '995 Patent -- for about three years and four months. Again, Warner-Lambert took the position that the '893 Patent covered the isolated R-trans enantiomer, atorvastatin calcium.

173. Warner-Lambert informed the PTO that (i) the FDA had approved Lipitor, (ii) the active ingredient in Lipitor was atorvastatin calcium, and (iii) atorvastatin calcium was claimed by the '893 Patent. Warner-Lambert represented that the '893 Patent claimed atorvastatin calcium as a new chemical entity (Claims 1-4), as a pharmaceutical composition (Claim 8), and as a method to inhibit cholesterol biosynthesis (Claim 9).

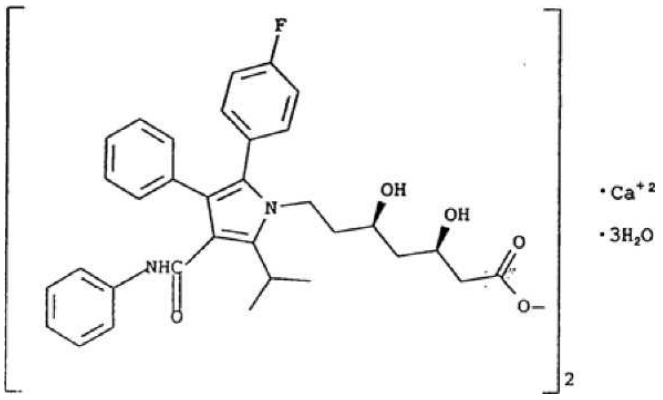
174. Claim 1 requires "a compound of structural formula I" or "a hydroxyl acid or pharmaceutically acceptable salt thereof, corresponding to the opened lactone ring of the compounds of structural formula I above." In the extension application, Warner-Lambert claimed that Lipitor is a pharmaceutically acceptable salt of structural formula I, and thus covered by Claim 1 of the '893 Patent:

Lipitor is a pharmaceutically acceptable salt (i.e., calcium salt) of the hydroxy acid corresponding to the opened lactone ring of a compound of structural formula I. Lipitor has the general structure:



where; **X** is **-CH$_3$CH$_2$-**
Ri is 4-**f**luorophenyl;
R$_2$ is phenyl;
R$_3$ is **-CONH-**phenyl; and
Rj is **1**-methylethyl, an alkyl group having three carbon atoms.

Lipitor™ thus has the specific chemical structure



175. The PTO granted the patent term extension. With both an extension for the time spent pursuing FDA approval of Lipitor under Section 156, and then for pediatric testing pursuant to the statutory provisions of the FDCA providing for additional marketing exclusivity, the '893 Patent ultimately expired on March 24, 2010.

176. Warner-Lambert also sought and obtained a six-month extension for pediatric testing for the '995 Patent pursuant to the FDCA. As a result, the expiration date of the '995 Patent was June 28, 2011.

177. The '893 Patent ultimately provided more than thirteen years of patent exclusivity to market and sell branded Lipitor -- from the 1997 launch until March of 2010. The '995 Patent -- fraudulently obtained by Warner-Lambert from the PTO -- tacked on, if enforced by Warner-Lambert or its successors, additional freedom from generic Lipitor competition.

3. In 1997, Warner-Lambert and Pfizer Launched Lipitor

178. Prior to commercialization, Warner-Lambert decided to employ a "saturation" approach to selling Lipitor. The intent of the "saturation" strategy was to have as many sales representatives as possible contacting physicians. As Anthony Wild, Warner-Lambert Pharmaceutical Sector President, explained, "[t]he more soldiers you have out there, the more guns, the more likely you are to achieve your ends." Warner-Lambert clearly understood that the sales force was a key success factor in any drug's performance, but a 1995 sales force deployment study revealed that the Warner-Lambert's sales force was inadequate in size and focus to effectively launch Lipitor.

179. Warner-Lambert chose Pfizer to assist in marketing Lipitor. Warner-Lambert and Pfizer outgunned the competition with the largest sales force ever. Between Warner-Lambert and Pfizer, more than 2,200 sales representatives were believed to be selling Lipitor during its launch in the U.S.

180. Lipitor reached $1 billion in domestic sales within 12 months of its January 1997 launch. By the end of 1998, Lipitor was available for sale in 50 countries. In October 1997, 30% of all new statin prescriptions were written for Lipitor.

F. The Pfizer Defendants' Litigation Against Ranbaxy Based on the '995 Patent

181. Ranbaxy was the first to file an ANDA for generic Lipitor. On August 19, 2002, Ranbaxy filed ANDA 76-477, seeking approval to sell a generic version of Lipitor in the 10, 20, 40,

and 80 mg tablet strengths.

182. As the first to file a substantially-complete ANDA for generic atorvastatin calcium, Ranbaxy was entitled to 180 days of marketing exclusivity under the then-effective provisions of the FDCA. No other ANDA applicant for generic Lipitor could receive FDA approval until the expiration of Ranbaxy's period of marketing exclusivity, which would not commence running until the earlier of either the inception of Ranbaxy's actual commercial marketing or one or more court decisions obtained by Ranbaxy or another ANDA filer that the patents listed in the FDA's "Orange Book" as claiming Lipitor were invalid or not infringed.

183. In or around February of 2003, Ranbaxy sent two Paragraph IV certifications to the Pfizer Defendants with respect to all patents listed in the Orange Book, including the '995 Patent. In them, Ranbaxy asserted that no valid patent claims covering Lipitor would be infringed by the sale, marketing, or use of Ranbaxy's ANDA product.

184. In response, the Pfizer Defendants, within the 45-day period provided by the Hatch-Waxman statutory scheme, filed an action in the United States District Court for the District of Delaware, alleging that Ranbaxy's ANDA product would infringe the '893 and '995 Patents.

185. From 2003 to 2006, the Pfizer Defendants' infringement litigation against Ranbaxy based upon the '893 and '995 Patents progressed through discovery, a trial, and an eventual appeal and decision by the United States Court of Appeals for the Federal Circuit. At the time the district court rendered its decision regarding the '995 Patent in December of 2005, neither the district court nor Ranbaxy had the benefit of portions of critical evidence regarding the fraudulent procurement of the '995 Patent that is set forth above.

186. On November 2, 2006, the Court of Appeals reversed the lower court's decision regarding the '995 Patent, determining that claim 6, the sole claim that the Pfizer Defendants

claimed Ranbaxy's ANDA product infringed, was technically invalid. The Federal Circuit refused to address the district court's other determinations regarding the '995 Patent. The Federal Circuit affirmed the ruling that the '893 patent was valid and would be infringed by Ranbaxy's product.

187. Based upon the Court of Appeals' mandate, the district court, on November 7 and 30, 2006, amended its Final Judgment Order to enjoin the effective date of any approval of Ranbaxy's ANDA for generic Lipitor until March 24, 2010, the expiry of the '893 Patent, and to remove from its Final Judgment Order any prohibition of effective FDA approval of Ranbaxy's ANDA based on the '995 Patent. On information and belief, the district court's Final Judgment Order, as amended, was sent by the Pfizer Defendants and Ranbaxy to the FDA.

G. Pfizer Sought Reissuance of the Fraudulently-Procured '995 Patent

188. In the absence of Warner-Lambert's fraud on the PTO, the '995 Patent would never have issued. Without its issuance in 1993, no reissue proceeding for the '995 Patent in 2007-2009 would have occurred. Without the reissue proceedings, the reissue patent that emerged from that proceeding, reissue Patent RE-40,667 (the "667 Patent"), would not exist. As a result, the PTO's eventual decision on the reissue proceedings is irrelevant to this antitrust action.

189. The reissue proceedings do, however, confirm what Pfizer had long known: the biologic data submitted as part of the application for the '995 Patent was false, inaccurate, incorrect, and riddled with errors. And by buying off Ranbaxy's opposition to the reissuance of the '995 claims, along with a sleight-of-hand with respect in its submissions to the PTO, Pfizer got the PTO to finally allow, albeit incorrectly, several claims of the '995 Patent as the '667 Patent.

190. In January 2007, in the wake of the 2006 Federal Circuit ruling invalidating the vital Claim 6 of the '995 Patent on technical grounds, Pfizer sought reissuance of the '995 Patent from the PTO "to correct a technical defect in some of the patent claims." In doing so, Pfizer sought to

limit the PTO's review to a determination of whether the newly redrafted claims (to correctly construct dependent or independent claims) would satisfy the construction rules of the applicable patent laws.

191. While Pfizer sought only to correct a technical defect, it knew that it potentially faced significant hurdles with respect to the validity of the '995 Patent. It knew that the PTO or others might raise the far more substantive problem that the '995 Patent was simply an obvious extension of the original '893 Patent (and that the data to support a finding of surprising or unexpected activity of the enantiomer was false). By this time in early 2007, the '995 Patent and its nearly identical foreign counterparts had been the subject of considerable litigation, not only in the federal district court *Ranbaxy* proceeding (with its limited scope of appellate review), but also in other countries throughout the world. Through these foreign proceedings, Pfizer learned that it could no longer get away with publicly relying upon the falsified biological data to support a claim that the R-trans enantiomer of atorvastatin was ten times more active than racemic atorvastatin (or that it was any more active than the expected activity of twice that of the racemate). As a result, in communications with the PTO, Pfizer expressly disavowed the reliability of the 1989-1993 biological data as a basis to reissue any of the claims in the '995 Patent.

192. On January 16, 2007, Dr. Roth and the Pfizer Defendants submitted a reissue application for claim 6 of the '995 Patent. The applicants did not amend or modify the '995 Patent specification as part of the reissue proceedings. Dr. Roth's remarks include a list of the "objective evidence" that "completely refutes any suggestion of obviousness." But the list did **not** include the purported surprising effectiveness of the R-trans enantiomer or a purported ten times greater activity of the R-trans enantiomer than the racemate.

193. An Informational Disclosure Statement of the same date states:

> Subsequent to the Federal Circuit's decision, while preparing for trial in Australia on a '995 counterpart, Pfizer first learned of **significant errors** in the COR results which neither Pfizer nor the parties adverse to it had discovered before. This discovery led Pfizer to advise the Federal Circuit that COR data could not be relied on to compare the relative activity of compounds — see Exhibit 9, page 10, fn 2. Thus **any earlier reference in Pfizer's findings, conclusions and brief to relative activity among compounds based on the COR test is withdrawn and is not relied on in these reissue proceedings. Pfizer does not at this point in the reissue rely for patentability on any comparisons based on CSI.** Neither CSI nor COR data were relied on by either U.S. court in reaching their decisions regarding the validity of '995 claim 6.

The Pfizer Defendants similarly stated: "Pfizer does not now rely on any . . . data [comparing between and among calcium salts and other salts of atorvastatin and its racemates] in support of patentability."

194. On June 7, 2007, as part of reissue proceedings on the '995 Patent, the Pfizer Defendants submitted a Second Informational Disclosure Statement that discusses "Foreign Proceedings on '995 Counterparts" and attached additional materials produced as part of certain non-U.S. proceedings. The Pfizer Defendants acknowledged therein that the biological data submitted in support of their patent applications -- in the CSI Table, the Roth Declaration, and the foreign "'995 counterparts" -- was inaccurate (emphasis added):

> [A]pplicant is submitting these documents to permit the Examiner to consider their potential materiality. Further, many of these documents . . . contain biological data or summaries of biological data, and **some of that biological data is now understood to be inaccurate** (due to transcription errors, calculation errors, experimental errors, etc.). Applicant is not submitting **corrected** biological data at the present time because, as applicant has emphasized repeatedly in these reissue proceedings, applicant is not currently relying on the biological data for patentability.

195. Elsewhere in the reissue proceedings, Dr. Roth and the other Pfizer Defendants referred to the biological data at issue in the Australian and Canadian patent litigation as "biologic data that Pfizer **then** argued showed that the atorvastatin enantiomer had unexpected and surprising

inhibition of cholesterol biosynthesis in-vitro in comparison to the racemic form of atorvastatin," while reiterating that they "**are not relying on any of the biological data as a basis for the patentability of the pending claims at the present time.**" Similarly, Dr. Roth and the other Pfizer Defendants stated, "[a]pplicant is not submitting **corrected** biological data at the present time because, as applicant has emphasized repeatedly in these reissue proceedings, applicant is not currently relying on the biological data for patentability."

196. At one point in the reissue proceedings, the examiner made a mistake and relied on the biological data to overcome an obviousness rejection:

> Claims 6, 13 and 14 have not been rejected as being obvious as the declaration of Bruce D. Roth filed February 25, 1991 discloses unexpected properties which would overcome any 35 USC 103(a) rejection of claims 6, 13 and 14 as atorvastatin calcium was shown to have activity greater than fifty-fold more than that of the S-trans and at least ten-fold more than that of the racemate.

197. Pfizer knew it could no longer allow the PTO to use its falsified biological data. As a result, it "reiterated [to the PTO] that they are not presently relying on any of the biological data (including the data contained in the Roth Declaration) as support for the patentability of claims 6, 13 and 14." It stated:

> Although applicant believes that the evidence provided in the Roth Declaration is sound, and is in no way disclaiming this data, it does not believe that it is necessary to consider such evidence in view of the present record . . . applicant respectfully requests that the Examiner withdraw her reliance on the data in the Roth Declaration and focus instead on the overwhelming evidence of secondary considerations that are discussed above.

The referenced secondary considerations include the argument based on Lipitor's commercial success.

198. On April 24, 2008, the PTO issued a non-final rejection of claims 6, 13, and 14. In so doing, the Examiner stated, "[a]s the data contained in the Roth declaration has not been relied on by Applicant in the instant reissue and is not a comparison of the claimed subject matter

(atorvastatin calcium) to the closest prior art, the examiner withdraws the reliance on the data in the Roth Declaration to overcome an obviousness rejection of reissue claims 6, 13 and 14." Instead, the Examiner relied on secondary considerations identified by the Applicants, namely Lipitor's commercial success.

199. On April 6, 2009, the PTO reissued claims 6, 13, and 14 of the '995 Patent as the '667 Patent.

200. The PTO based its ruling to grant the re-issuance of the '995 Patent not on the basis of the biological studies and representations made by Warner-Lambert (even though a version of the CSI assay data remains in the specification for the patent), but instead on the basis of the Pfizer Defendants' arguments that the commercial success of Lipitor shows that the '995 Patent could not have been obvious.

201. Were it not for the Pfizer Defendants' fraud on the PTO in 1993, there would never have been a '995 Patent in the first place, or any commercial success attributable to the '995 Patent for the patent examiner to rely upon to reissue the '995 Patent.

H. The Pfizer Defendants Filed a Sham "Citizen Petition" with the FDA

202. The Pfizer Defendants' patent infringement lawsuit against Ranbaxy stayed final FDA approval of Ranbaxy's generic Lipitor ANDA for 30 months. The 30-month stay ended in or about August of 2005.

203. The Pfizer Defendants knew that the end of the 30-month stay would permit the FDA to issue final approval to Ranbaxy's generic Lipitor ANDA (which had been pending since August of 2002), which in turn would permit the start of generic Lipitor competition. The Pfizer Defendants wanted to delay such final approval for as long as possible.

204. As a matter of procedure and practice, the FDA will not issue a tentative approval of

an ANDA if there are no unexpired exclusivities applicable to the branded drug. In such cases, the FDA will issue only a final approval.

205. As August of 2005 approached, there was a single ANDA on file for generic Lipitor: Ranbaxy's. From their litigation against Ranbaxy, the Pfizer Defendants knew and believed that Ranbaxy's ANDA specified the use of amorphous atorvastatin calcium as the active pharmaceutical ingredient in its generic Lipitor product.

206. To delay final FDA approval of Ranbaxy's ANDA following the end of the 30-month stay, the Pfizer Defendants wrote to the FDA on July 28, 2005, not for a proper purpose, but instead in an attempt to slow down the FDA approval process for Ranbaxy's ANDA. The Pfizer Defendants had no more information on July 28, 2005 than they had months earlier about Ranbaxy's ANDA; they purposely submitted their letter to the FDA shortly before the 30-month stay from the patent litigation was to expire in an attempt to obtain additional delay as a result of the submission of that letter -- delay which, the Pfizer Defendants hoped, would continue after the 30 month stay expired.

207. The Pfizer Defendants entitled their letter to the FDA "Generic Versions of Atorvastatin." In it, the Pfizer Defendants said that they were "concerned" that ANDA applicants for generic Lipitor were using amorphous atorvastatin calcium, which, the Pfizer Defendants claimed, "may be susceptible to higher levels of impurities than are found in Lipitor and that may degrade more quickly and thus have inferior stability compared to Lipitor."

208. The Pfizer Defendants said that this "may raise questions about the approval of" ANDAs for generic Lipitor. The Pfizer Defendants asked the FDA to "carefully scrutinize" such "potential differences in quality . . . before the atorvastatin variants are approved under ANDAs." The Pfizer Defendants said that "the risk of reduced quality in the generic product," due to the use

of amorphous atorvastatin, was "clear" and that Ranbaxy's ANDA should be "reviewed with considerable skepticism."

209. The letter to the FDA was signed by a Pfizer scientist, a vendor Pfizer used that "provides analytical services to the pharmaceutical industry," and was copied to Jeffrey B. Chasnow, a lawyer in Pfizer's legal department.

210. The Pfizer Defendants' true purpose for sending their letter to the FDA was to cause the FDA to take a longer time in reviewing Ranbaxy's ANDA for generic Lipitor and thereby delay final approval once the 30-month stay had ended. Ranbaxy's generic product used amorphous atorvastatin calcium to design around the Pfizer Defendants' Orange Book-listed '156 Patent, which claimed crystalline (not amorphous) forms of atorvastatin.

211. On August 30, 2005, the FDA contacted the Pfizer Defendants and told them that the procedure for communicating with the FDA on such issues was to file a so-called "citizen petition."

212. On November 7, 2005, the Pfizer Defendants re-filed their July 28 letter as a citizen petition. The Pfizer Defendants rearticulated their request: "Pfizer asks that FDA consider the information provided in the July 28 letter, together with any additional information that may be submitted to the petition file by Pfizer or others, in FDA's decisions concerning approvals of generic versions of atorvastatin."

213. As a matter of procedure and practice, the FDA did not, at any relevant time, issue approvals to ANDA filers when citizen petitions were pending.

214. While the Petition suggested that amorphous formulations should be looked at with considerable skepticism because they may be less pure and less stable than Lipitor (which contained crystalline atorvastatin), the Pfizer Defendants themselves used amorphous atorvastatin calcium for virtually all development activities for Lipitor, including numerous studies. Therefore, the Pfizer

Defendants knew that safe and stable versions of atorvastatin calcium could be -- and had been -- made using the types of amorphous formulations that the generics would use. The Pfizer Defendants switched to the crystalline form of atorvastatin calcium only in or around June of 1995, late in the development of Lipitor, just prior to its commercialization. The Pfizer Defendants did so unilaterally, not at the request of the FDA. On information and belief, the Pfizer Defendants did so in anticipation of the issuance of the '156 Patent, which claimed crystalline forms of atorvastatin; it did not switch from the amorphous formulations it had been using for years based on concerns that the amorphous formulations were unsafe, ineffective or incapable of meeting the FDA requirements regarding impurities or stability.

215. Having studied the amorphous form thoroughly, the Pfizer Defendants knew, and told the FDA in or around June of 1995, that there were no clinical safety or efficacy implications related to using the amorphous, as compared with the crystalline, form. As it turned out, toxicity was a concern for the *crystalline* form of atorvastatin calcium that the Pfizer Defendants ultimately used, not the amorphous form that the Pfizer Defendants abandoned (and Ranbaxy proposed to use).

216. The Pfizer Defendants submitted no evidence to the FDA that showed or even suggested that Ranbaxy's ANDA product, because it used amorphous atorvastatin calcium as the drug substance:

a. was not (or would not be) pharmaceutically equivalent or bioequivalent to branded Lipitor;

b. could not or would not satisfy the conditions for approval under the FDCA; and/or

c. could not or would not be capable of being processed or manufactured under current good manufacturing practices ("cGMP").

217. Instead, the Pfizer Defendants simply ignored the FDA's prior stated positions

concerning polymorphism, and submitted their Petition in contradiction of these principles.

218. Fifteen years before the Pfizer Defendants submitted their Petition, in 1992, the FDA specifically rejected a regulatory proposal that would have required an ANDA applicant to show that the active ingredient *(i.e.,* the drug substance) in its generic drug product and the active ingredient *(i.e.,* the drug substance) in the corresponding brand drug "exhibit the same physical and chemical characteristics, *that no additional residues or impurities can result from the different manufacture or synthesis process,* and that the stereochemistry characteristics and *solid state forms of the drug have not been altered*" (emphases added) (the "1992 Regulatory Rejection"). Therefore, the FDA had already determined, more than a decade earlier, that differences in drug substance polymorphic forms, including differences in residues and impurities, do not cause drug substances to be considered different active ingredients for the purposes of ANDA approvals within the meaning of the FDCA and FDA regulations.

219. Over three years before the Pfizer Defendants sent their letter to the FDA, the FDA had already declined to utilize special or additional scrutiny or specifications when reviewing ANDAs for drug products that utilized different polymorphic forms of the active pharmaceutical ingredient.

220. On February 15, 2002, in a publicly-available denial of another company's citizen petition of which the Pfizer Defendants had actual and/or constructive knowledge (the "2002 Decision"), the FDA stated that "FDA's view is that the [FDCA], existing regulations, preamble statements, and the FDA publication *Approved Drug Products With Therapeutic Equivalence Evaluations (Orange Book)* [already] provide an adequate basis to guide the Agency's decision making on ANDAs seeking approval of a generic drug product whose active ingredient has a different physical form than the active ingredient in the reference listed drug." The generic ANDA

filer in the 2002 Decision was, as here, Ranbaxy.

221. Specifically, the FDA ruled in its 2002 Decision that "FDA's review of any ANDA [already] includes ensuring that the ANDA applicant has the appropriate controls in place with respect to the drug substance and drug product. In the FDA's view, Ranbaxy has appropriate controls with respect to the drug substance and the drug product." Thus, the FDA expressly declined to apply special or additional scrutiny or specifications to the review of an ANDA when a different form of the active pharmaceutical ingredient was used by the proposed ANDA product.

222. The FDA explained in the 2002 Decision that what mattered in connection with ANDA approval was the performance of the *drug product* (not the active ingredient (i.e., the *drug substance* in isolation)) under existing FDA standards:

> If a polymorph displays different properties such as melting point, solubility, and stability, these characteristics could ultimately have an impact on the approval of an ANDA for a proposed generic *drug product.* These characteristics could ultimately affect the approval because the approval is based not only on whether the active ingredient in the proposed generic drug product is the "same" as the active ingredient in the reference listed drug, but also on whether the proposed generic *drug product* is the same as the reference listed drug. FDA will approve a generic drug product if the ANDA applicant provides, among other things, sufficient information to show that the generic *drug product* is the "same" as the reference listed drug. However, if the active ingredient of a proposed generic drug product were to have a different polymorphic form than the active ingredient in the reference listed drug, and this difference affected the behavior or certain characteristics of the drug product, then FDA might not approve the generic drug product, despite the fact that the proposed generic drug product contained the same active ingredient as the reference listed drug.

223. The FDA also announced in the 2002 Decision that:

a. "[a] difference in the physical form of an active ingredient in a generic drug product from the physical form of the active ingredient in the reference listed drug, including a difference in the crystalline structure of the active ingredient, does not bar the approval of a proposed generic drug product";

b. "[f]or a generic drug product to be regarded as having the same active ingredient under [21 C.F.R] § 314.92(a)(1), the drug substance in a proposed generic drug product need not have the same physical form as the drug

substance in the reference listed drug"; and

c. "FDA's scientific expertise and experience have shown that a difference in the physical form of the active ingredient in a generic drug product from the physical form of the active ingredient in the reference listed drug, including a difference in the crystalline structure of the active ingredient, does not prevent a finding of therapeutic equivalence."

224. Since at least 2003, prominent scientists within the FDA's Center for Drug Evaluation and Research have stated that there is "no scientific basis" upon which to conclude that an ANDA applicant's use of a drug substance polymorph differing from that in the corresponding brand drug should preclude the ANDA applicant from demonstrating drug product manufacturability, bioequivalence, and stability. Those same FDA scientists also stated, at or around the same time, that there was "no scientific or regulatory basis" for requiring a generic drug product to use the same polymorphic form as the innovator.

225. The same FDA scientists also stated, at or around that same time, that despite the potential effect that polymorphism may have on drug stability, **"because drug product stability is affected by a multitude of other factors, including formulation, manufacturing process, and packaging, it is the stability of the *drug product,* not the *drug substance,* that is the most relevant measure of drug quality."** Thus, existing FDA scrutiny of ANDAs was sufficient when polymorphic forms of drug substances were involved, according to the FDA. "[U]nder cGMPs, the sponsor of the ANDA must still provide evidence of manufacturing process validation and demonstrate that the drug product can be manufactured reproducibly, while meeting all the required in-process, release, and stability specifications," the FDA scientists said.

226. In a December 2004 draft guidance (the "2004 Polymorph Draft Guidance"), the FDA explained that polymorphism was already accounted for by existing FDA regulations and ANDA review procedures:

> In addition to meeting the standards for identity, each ANDA applicant is required to demonstrate that, among other things, the drug product exhibits sufficient stability and is bioequivalent to the [corresponding brand drug]. While the polymorphic form can affect drug product stability and bioequivalence, these performance characteristics are also dependent on the formulation, the manufacturing process, and other physicochemical properties *(e.g.*, particle size, moisture) of both the drug substance and formulation excipients. Using a drug substance polymorphic form that is different from that of the [corresponding brand drug] may not preclude an ANDA applicant from formulating a generic drug product that exhibits bioequivalence and stability, and **the drug substance in the generic drug product need not have the same polymorphic form as the drug substance in the [corresponding brand drug].**

(Emphasis added.)

227. The FDA reiterated in the 2004 Polymorph Draft Guidance what FDA scientists had said in 2003: "**because *drug product* stability is affected by a multitude of other factors, including formulation, manufacturing process, and packaging, it is the stability of the *drug product,* and not stability of the *drug substance* polymorphic form that should be the most relevant measure of drug quality"** (emphasis added).

228. Although given the opportunity to comment upon the 2004 Polymorph Draft Guidance, the Pfizer Defendants did not do so.

229. At all relevant times, the preface to the FDA "Orange Book" provided that "[a]nhydrous and hydrated entities, as well as different polymorphs, are considered pharmaceutical equivalents[.]"

230. Any reasonable drug company, and certainly Pfizer as the largest drug company of all, would know the FDA's established policies and practices regarding polymorphic forms of active pharmaceutical ingredients prior to sending a letter and Petition to the FDA implicating those policies and practices.

231. The Pfizer Defendants' letter and Petition were objectively baseless and interposed solely to create an obstacle to the final FDA approval of Ranbaxy's generic Lipitor ANDA. No

objectively reasonable petitioner would have expected success on the merits of the Pfizer Defendants' letter or Petition. The Pfizer Defendants' letter and Petition lacked any reasonable regulatory, scientific, medical, or other reasonable basis. The Pfizer Defendants' letter and Petition lacked any evidence that lent support to their assertions or that bore on the approvability of Ranbaxy's ANDA product. The Pfizer Defendants' letter and Petition stood no chance of affecting FDA policy or procedure. The Pfizer Defendants' Petition was flatly contrary to the FDA's expressed views regarding drug substance polymorphic forms, and did not reasonably argue (or argue at all) for a change in those expressed views. In short, the Pfizer Defendants' letter and Petition were nothing more than a thinly-veiled effort to send the FDA on a wild goose chase in the hopes of delaying Ranbaxy's final ANDA approval.

232. On November 30, 2011, the same date that Ranbaxy could first enter the market with generic Lipitor pursuant to its Agreement with the Pfizer Defendants, the FDA issued its formal written denial of the Pfizer Defendants' Petition.

233. The FDA denied Pfizer's Petition because, just as it had already said in the 1992 Regulatory Rejection, the 2002 Decision, the 2004 Polymorph Draft Guidance, and repeatedly thereafter, ANDA applicants need not show that their active ingredients have no additional residues, impurities, or solid state forms relative to the active ingredient in the corresponding brand drug.

234. Likewise, as the FDA had repeatedly said before, the FDA's existing policies and procedures were adequate to identify any ANDA product that used different polymorphs than the corresponding brand product, determine whether that difference resulted in any differences in measures such as purity or stability, and if such differences existed, whether the purity and stability data for the ANDA product satisfied the FDA's longstanding standards for such measures.

There was nothing about this process that required any additional skepticism or special consideration by the FDA. Thus, the FDA again expressly declined to apply special or additional scrutiny to the review of such ANDAs:

> **We believe that the Agency's existing recommendations to industry on assessing active ingredient sameness and stability of polymorphic forms of drug substances,** as well as those on comprehensive chemistry, manufacturing, and controls (CMC) and impurities, are adequate to enable an ANDA applicant to address any potential drug product stability, degradation, and impurity issues associated with the amorphous form of atorvastatin. **We also believe that the Agency's existing policies and review practices are sufficient for a critical evaluation of the variables that have the potential to affect drug product quality of drug products containing amorphous atorvastatin.**
>
> * * *
>
> In the preamble to the final rule implementing the generic drug approval provisions of the Hatch Waxman Amendments, FDA specifically rejected the suggestion that the Agency adopt a requirement that active ingredients "exhibit the same physical and chemical characteristics, that no additional residues or impurities can result from the different manufacture or synthesis process; and that the stereochemistry characteristics and solid state forms of the drug have not been altered."

235. Moreover, in denying the Pfizer Defendants' Petition, the FDA again stated, just as it had done in the 2004 Draft Polymorph Guidance, that "**the inherent stability of the *drug substance* polymorphic form should not be the primary consideration in making a determination of *product* stability. Rather, the stability of the generic atorvastatin drug *product* is the most relevant measure of drug product quality**" (emphasis in original).

236. Again, these were not new positions on the part of the FDA. Instead, the Pfizer Defendants' Petition was flatly contrary to, and willfully ignored, the FDA's previous decisions and previously-expressed views in the 1992 Regulatory Rejection, the 2002 Decision, the 2004 Polymorph Draft Guidance, and repeatedly thereafter. Given those previous FDA decisions and previously-expressed views, the Pfizer Defendants had no objectively reasonable basis to file the letter or Petition.

237. The FDA did not earlier issue its formal written denial of the Pfizer Defendants' Petition for the same reason that the FDA did not issue its formal written approval of Ranbaxy's ANDA until November 30, 2011: the FDA knew from Ranbaxy that the Agreement prevented Ranbaxy from coming onto the market until November 30, 2011. There was no need for the FDA to issue the formal written denial of the Pfizer Defendants' Petition earlier than November 30, 2011.

I. The Pfizer Defendants and Ranbaxy Entered Into the Illegal Horizontal Market Allocation Agreement

238. The Pfizer Defendants and Ranbaxy knew and/or believed that Ranbaxy was the first filer of an ANDA for generic Lipitor. As a result, the Pfizer Defendants and Ranbaxy both knew and/or believed that Ranbaxy would enjoy the ability to market its generic Lipitor for 180 days free from competition from other ANDA filers.

239. The Pfizer Defendants and Ranbaxy also knew that Ranbaxy's 180-day exclusivity would give Ranbaxy the ability -- simply by refraining from launching its own generic Lipitor or from relinquishing the right to its 180-day exclusivity period -- to prevent other generic competitors from entering the United States market.

240. Consequently, all the Pfizer Defendants needed to do to delay all generic Lipitor competition was enter into an agreement with Ranbaxy under which Ranbaxy would agree to delay the launch of its generic version of Lipitor. As Defendants knew, such an agreement would create a nearly-insurmountable obstacle to generic competition for all ANDA filers for the duration of any such agreement.

241. That is just what the Pfizer Defendants and Ranbaxy did. On June 17, 2008, after the only claim of the '995 Patent upon which the Pfizer Defendants had sued Ranbaxy had been declared invalid, the Pfizer Defendants and Ranbaxy, ostensibly to settle patent litigation, entered into an unlawful "pay-for-delay" Agreement.

242. The Agreement constituted an unlawful contract, combination and conspiracy to allocate the entire United States market for atorvastatin calcium to the Pfizer Defendants until November 30, 2011.

243. Pursuant to the Agreement, Ranbaxy agreed that it would neither (a) compete directly with the Pfizer Defendants with a generic Lipitor in the United States market nor (b) selectively waive or relinquish its first-to-file 180-day marketing exclusivity so as to permit any other ANDA filer to compete directly against the Pfizer Defendants with a generic Lipitor in the United States market until November 30, 2011. Absent the Agreement, Ranbaxy would have been highly motivated to pursue either of these courses, given the enormous profit opportunity generic Lipitor presented to Ranbaxy and other ANDA filers, and given the FDA's desire to permit ANDA filers to bring low-cost generic products to market as soon as possible.

244. In exchange for Ranbaxy's agreement not to launch (or authorize another ANDA filer to launch) generic Lipitor until November 30, 2011, the Pfizer Defendants gave Ranbaxy substantial consideration, including dismissal of a damage claim on the separate product quinapril hydrochloride (Accupril) that Ranbaxy had launched at risk, and the right to market generic Lipitor in at least eleven foreign markets.

245. The Pfizer Defendants also purported to give Ranbaxy protection from infringement liability in connection with a variety of patents, but that "consideration" was a sham, illusory, and merely inserted into the Agreement to disguise the illegal horizontal agreement to allocate the entire United States market for atorvastatin calcium.

246. In fact and at law, no reasonable litigant would believe that any patent even colorably put Ranbaxy (or any other relevant ANDA filer) in danger of liability for infringement of any legitimately-obtained patent past March of 2010 (when the '893 Patent expired), because no

legitimately-obtained patent posed any objectively reasonable or realistic threat of infringement liability to Ranbaxy (or any other relevant ANDA filer) for making or selling generic Lipitor, other than the '893 Patent.

247. An infringement case against Ranbaxy (or any other ANDA filer), based upon any legitimately-obtained Lipitor patent that expired after March 24, 2010, would have been (and was, with respect to, for example, Pfizer's suit claiming infringement of Pfizer's process patents) an objectively baseless sham. (And even if it is assumed, contrary to fact, that the '995 Patent was obtained legitimately, it expired by June 28, 2011, five months before November 30, 2011.) As a result, the Agreement gave the Pfizer Defendants protection from generic Lipitor competition beyond the exclusionary power and potential of any Lipitor patent. Nor did the Pfizer Defendants or Ranbaxy subjectively believe there was any such threat of infringement from such patents.

248. The Pfizer Defendants were well aware of the lack of exclusionary power of its intellectual property beyond June of 2011, when the fraudulently-procured '995 Patent was set to expire. In 2005, before the Agreement existed, Pfizer's former Chairman and CEO stated:

> There are dozens of generic drug manufacturing companies with a red circle around June 28, 2011. That's the day the patent for our anti-cholesterol medication Lipitor expires. . . . Shortly thereafter a number of generic alternatives to Lipitor will be introduced and consumers will have a choice of generic tablets containing atorvastatin calcium[.]

249. Of course, only the fraudulently-procured '995 Patent expired in June of 2011. Other patents purportedly covering Lipitor -- namely the Unasserted Formulation Patents, the '156 Patent, and the Process Patents (more specifically described above and below) -- would expire between 2013 and 2017. If the Unasserted Formulation Patents, the Process Patents, and/or the '156 Patent had any potential to legitimately keep generics off the market, Pfizer's CEO would not have ignored them and the literally tens of billions of dollars they would have conferred on his

company. His statement that June 28, 2011 is the key date only makes sense if one recognizes -- as the Pfizer Defendants did -- that the Unasserted Formulation Patents, the Process Patents, and the '156 Patent could not block generics from entering.

250. And as of the date of the Agreement, the only means by which the Pfizer Defendants could have prevented a launch by Ranbaxy of generic Lipitor on or after March 24, 2010 (or June 28, 2011) was by seeking an injunction. As the Pfizer Defendants knew in 2008, obtaining such an injunction would have been impossible, because it would have required a showing that the Pfizer Defendants were likely to succeed on the merits of baseless patent infringement claims.

1. The "Process Patents"

251. As of the date of the Agreement, the only pending patent litigation by the Pfizer Defendants against Ranbaxy involving Lipitor was litigation alleging infringement of specific processes for making atorvastatin calcium, taught in U.S. Patent Nos. 6,274,740 (the "'740 Patent") and 6,087,511 (the "'511 Patent") (together the "Process Patents").

252. The Pfizer Defendants had no realistic likelihood of meeting their burden of establishing that Ranbaxy infringed these Process Patents. The Process Patents afforded the Pfizer Defendants no power to exclude Ranbaxy (or any other ANDA filer) from the United States market for atorvastatin calcium. No objectively reasonable litigant would have believed otherwise. The Pfizer Defendants and Ranbaxy both knew and believed this, as well.

253. In July 2000 and August 2001, the PTO issued the Process Patents.

254. Salts of atorvastatin are polymorphic. The polymorphs can be either crystalline or amorphous. Crystalline forms have different arrangements and/or conformations of the molecules in the crystal lattice. Amorphous forms consist of disordered arrangements of molecules that do not possess a distinguishable crystal lattice.

255. The '740 Patent issued from U.S. patent application no. 09/657,469 (the "'469 Application"). The '469 Application was a continuation of U.S. patent application No. 09/453,189, which was itself a continuation of U.S. patent application No. 08/983,369 (the " '369 Application"). The '369 Application issued as the '511 Patent. As a continuation of the '511 Patent, the '740 Patent has a virtually identical specification to the '511 Patent. Indeed, the Summary of the Invention sections of these two patents are identical, stating, in relevant part, as follows (emphasis added):

> [T]he present invention is a novel process for the preparation of amorphous atorvastatin and hydrates thereof which *comprises:*
>
> (a) dissolving ***crystalline Form I atorvastatin*** in a non-hydroxylic solvent; and
>
> (b) removing the solvent to afford amorphous atorvastatin.

256. The Process Patents are narrow in scope. For a generic manufacturer's process to infringe either of these patents, the generic manufacturer must, *inter alia*, start by dissolving *crystalline Form I atorvastatin* in the specified solvent. If the manufacturing process dissolves into the solution any crystalline structure other than Form I in the specified solvent, or dissolves amorphous atorvastatin, the process does not and cannot infringe either of the Process Patents. The process must also meet each of the other claims of the Process Patents, as well.

257. Because of the narrow scope of the Process Patents, and the ample number of both amorphous and crystalline forms of atorvastatin that were available, a very large number of non-infringing alternatives existed to the technology claimed in the Process Patents. Indeed, the prior art, including the '893 Patent (covering the active ingredient of Lipitor, atorvastatin calcium), described numerous processes for making atorvastatin calcium that are prior art to the Process Patents and would invalidate the claims of the Process Patents if those claims read on the processes described in the '893 Patent.

258. The Pfizer Defendants themselves produced amorphous atorvastatin in their manufacturing processes before developing crystalline formulations such as Form I. There is no need for someone seeking to produce amorphous atorvastatin calcium to first produce Form I crystalline atorvastatin calcium.

259. The Pfizer Defendants were well aware that generic companies were seeking to develop generic versions of atorvastatin that did not infringe the Pfizer Defendants' patents, including the Process Patents. Indeed, it is common practice for experienced generic companies such as Ranbaxy to conduct patent searches during the drug development process, and to select drugs for further development that are covered by patents that the generic companies can readily design around.

260. Process patents are not required to be (and in fact cannot be) listed in the FDA's Orange Book, since they are not patents claiming an approved drug or an approved use of a drug. Therefore, the existence of the Process Patents did not create a regulatory impediment to generic entry, since ANDA filers are not required to file Paragraph IV certifications with respect to non-listed patents, and the Pfizer Defendants thus could not obtain an automatic 30-month stay of FDA approval of an ANDA by bringing a timely suit for infringement of the Process Patents.

261. Nor did the existence of the Process Patents create a legal impediment to generic entry. Because numerous non-infringing alternatives to the processes claimed in the Process Patents existed, there was no reasonable likelihood -- or any likelihood at all -- that the Pfizer Defendants would be able to use the Process Patents to obtain a court order enjoining ANDA filers, including Ranbaxy, from selling generic versions of Lipitor on the ground that they infringed the Process Patents.

262. Nevertheless, on or about March 24, 2008, the Pfizer Defendants filed a complaint in the United States District Court for the District of Delaware alleging that Ranbaxy infringed the Process Patents. The complaint contained only the most conclusory allegations of infringement. In particular, that complaint includes no factual allegations or support whatsoever establishing that Ranbaxy's process satisfied the various elements of the claims of the Process Patents, including (but not limited to) the use of crystalline Form I at the start of the manufacturing process. The complaint merely states as follows:

> 30. Upon information and belief, Ranbaxy's Atorvastatin Product is made or is intended to be made by a process which if practiced in the United States would infringe the '511 patent.
>
> * * *
>
> 41. Upon information and belief, Ranbaxy's Atorvastatin Product is made or is intended to be made by a process which if practiced in the United States would infringe the '740 patent.

263. These allegations were completely baseless as a matter of fact and law. There was no basis for the Pfizer Defendants to believe that Ranbaxy was unaware of the elements of the Process Patents. Nor was there any basis to believe that Ranbaxy did not develop a manufacturing process that purposely avoided infringing on those patents. Indeed, as alleged above, there were numerous forms of atorvastatin, other than the crystalline Form I specified in the Process Patents, that Ranbaxy could have (and, upon information and belief, did) use at the start of its manufacturing process. And, there was no need for Ranbaxy to first create a crystalline form of atorvastatin calcium to manufacture an amorphous form of atorvastatin calcium.

264. Moreover, the Pfizer Defendants were well aware, prior to filing their complaint alleging that Ranbaxy infringed the Process Patents, that Ranbaxy intended to use amorphous atorvastatin as a starting material in manufacturing another generic atorvastatin drug, Caduet (a combination of Lipitor and another drug, Norvasc). The Pfizer Defendants had no basis to believe

that Ranbaxy would not similarly use non-infringing amorphous atorvastatin, or another non-infringing form of atorvastatin, in its manufacturing process for its generic version of Lipitor. And there clearly would have been no reasonable basis to maintain the lawsuit alleging infringement of the Process Patents, if those lawsuits had been maintained absent the Agreement, as the Pfizer Defendants would have definitively learned through discovery early in that case that Ranbaxy's manufacturing process did not infringe the Process Patents.

265. The Pfizer Defendants' complaint alleging infringement of their Process Patents did not cite to any facts or evidence whatsoever to support the Pfizer Defendants' conclusory assertion that Ranbaxy's process met any, let alone all, of the elements of the Process Patents.

266. When the Pfizer Defendants and Ranbaxy entered into the Agreement, Pfizer dropped its complaint. During the pendency of their complaint, the Pfizer Defendants never produced any evidence to support their purely conclusory allegations that Ranbaxy infringed the Process Patents. Nor could they, since such allegations were false and baseless as a factual (and legal) matter.

267. As a result, the Process Patents had no exclusionary power vis-à-vis potential generic competitors, including Ranbaxy, because the Pfizer Defendants did not (and could not) prove the facts necessary to meet their burden of establishing infringement of each element of the Process Patents. Therefore, even though the Process Patents were presumed to be valid and enforceable, they had no exclusionary power because the Pfizer Defendants had no reasonable likelihood of meeting their burden of establishing that each element of those patents was infringed. In other words, the Pfizer Defendants could not use the Process Patents to exclude any generic competitor, including Ranbaxy, from the market.

268. Likewise, because Process Patents cannot be listed in the Orange Book, Pfizer could not (and did not) use the Process Patents to obtain an automatic 30-month stay of FDA approval of a pending ANDA.

2. The "Unasserted Formulation Patents" and the '156 Patent

269. At the time of the Agreement, the Pfizer Defendants also possessed other patents that purportedly covered certain forms of atorvastatin calcium, namely the Unasserted Formulation Patents (i.e., the '971 and '104 Patents) and the '156 Patent (which covered crystalline forms of atorvastatin). Like the Process Patents, neither the Unasserted Formulation Patents nor the '156 Patent provided the Pfizer Defendants with any legitimate power to exclude Ranbaxy (or any other ANDA filer) from the relevant market, because the Pfizer Defendants could not have met their burden of establishing that Ranbaxy (or any other ANDA filer) infringed the Unasserted Formulation Patents nor the '156 Patent.

270. The Pfizer Defendants had no realistic likelihood of obtaining a court order enjoining Ranbaxy (or any other ANDA filer) from selling its generic version of Lipitor based on infringement of the Unasserted Formulation Patents or the '156 Patent, something the Pfizer Defendants and Ranbaxy both knew and believed.

3. The Operation of the Agreement

271. Nevertheless, pursuant to the Agreement, Ranbaxy agreed not to sell its generic version of Lipitor in the United States until November 30, 2011 -- twenty (20) months after the '893 Patent (and any associated marketing exclusivities) was scheduled to expire, and five (5) months after the fraudulently-obtained '995 Patent was expected to expire if it was reissued.

272. Ranbaxy agreed to keep its generic version of Lipitor off the market until well after the legitimate exclusionary power of the Pfizer Defendants' patents had expired because it was paid

handsomely not to compete with the Pfizer Defendants. Specifically, upon information and belief (and based upon the limited public disclosure to date regarding the terms of the Agreement), Ranbaxy received at least the following compensation in exchange for its agreement to delay coming to market with its generic version of Lipitor in the United States: (1) permission to sell generic versions of Lipitor in at least eleven foreign markets, including Canada, Belgium, Netherlands, Germany, Sweden, Italy, and Australia; and (2) the dismissal of a damage claim on the separate product quinapril hydrochloride (Accupril) that Ranbaxy had launched at risk and that was unrelated to the Process Patents, the Unasserted Formulation Patents, and/or the '156 Patent.

273. As part of the Agreement, Ranbaxy also agreed not to challenge the validity of any Lipitor patent, including the '995 Patent, that was then the subject of reissuance proceedings. Pursuant to this Agreement, Ranbaxy dropped its challenge to the reissuance of the '995 Patent -- a challenge that had been successful prior to the date of the Agreement.

274. As explained above, in or around April of 2009, after Ranbaxy dropped its challenge, the PTO reissued the '995 Patent as the '667 Patent. The '667 Patent, like the '995 Patent, was expected to expire (and did expire) on June 28, 2011. Nevertheless, pursuant to the Agreement, which provided Ranbaxy with substantial compensation in exchange for its agreement not to compete, Ranbaxy could not sell its generic version of Lipitor until November 30, 2011, a full five months after the '667 Patent expired.

275. The Agreement was unlawful for at least the following reasons: (a) it constituted an illegal market allocation agreement, pursuant to which the Pfizer Defendants paid substantial monies to their competitor, Ranbaxy, in exchange for Ranbaxy's agreement to allocate the entire United States market for atorvastatin calcium to Pfizer through November 30, 2011; (b) it restricted competition in a manner, and to an extent, that exceeds the exclusionary power and potential of the

Pfizer Defendants' Lipitor patents; (c) it purported to settle patent infringement litigation that arises from a patent (the '995 Patent) that was procured by fraud upon the PTO; and (d) to the extent it purported to settle patent claims other than those found in the '893 and '995 Patents, any patent litigation against Ranbaxy for infringement of any Lipitor patent extending past June 28, 2011 was (with respect to the Process Patents), or would have been (with respect to the Unasserted Formulation Patents and the '156 Patent), baseless sham litigation that the Pfizer Defendants (and Ranbaxy) knew they would lose.

J. In Furtherance of the Agreement, the Pfizer Defendants Thwarted Other ANDA Filers from Triggering Ranbaxy's 180-Day First-to-File Marketing Exclusivity

276. The Agreement sought to prevent other ANDA filers from launching their own generic versions of Lipitor before Ranbaxy. Ranbaxy's anticipated 180-day marketing exclusivity as the first filer of a generic Lipitor ANDA meant that only Ranbaxy's own first commercial marketing of its ANDA product would trigger the 180-day period. Before the expiration of that 180-day period, other generic Lipitor ANDA filers could not market their generic versions of Lipitor.

277. Other ANDA filers could trigger Ranbaxy's 180-day exclusivity by obtaining one or more court decisions that the patents listed in the FDA "Orange Book" as claiming Lipitor are invalid or not infringed. If another ANDA filer were to obtain such a court decision, Ranbaxy's 180-day first-to-file marketing exclusivity would commence running, even if Ranbaxy had not yet begun commercial marketing of its ANDA product by that time, and even if Ranbaxy did not want its exclusivity to commence running.

278. Another way that other ANDA filers could circumvent Ranbaxy's 180-day exclusivity was by convincing the FDA to deprive Ranbaxy of its 180-day exclusivity period and

approve the ANDAs of other generic companies unimpeded by any 180-day period.

279. These two possibilities were of substantial concern to the Pfizer Defendants and Ranbaxy in 2008 when they reached the Agreement. The Pfizer Defendants did not want generic Lipitor competition earlier than the November 30, 2011 date provided in the Agreement, and Ranbaxy did not want any involuntary triggering or forfeiture of its anticipated, and enormously valuable, 180-day first-to-file marketing exclusivity. Such events would frustrate the Agreement, and threaten to diminish or eliminate the value of Ranbaxy's exclusivity. Both the Pfizer Defendants and Ranbaxy had a keen interest in ensuring that Ranbaxy's 180-day exclusivity was protected, to prevent other ANDA applicants for generic Lipitor from coming to market.

280. Therefore, to prevent the involuntary triggering of Ranbaxy's 180-day first-to-file marketing exclusivity prior to November 30, 2011, the Pfizer Defendants, pursuant to and in furtherance of the Agreement, engaged in a sustained campaign to thwart the efforts of generic manufacturers to obtain judgments of invalidity and/or non-infringement with respect to the Unasserted Formulation Patents.

281. To effectuate this campaign, the Pfizer Defendants settled cases prior to judgments on the merits, vigorously opposed the efforts of ANDA applicants to obtain declarations that the Unasserted Formulation Patents were invalid and/or not infringed, and otherwise engaged in a pattern of dilatory conduct designed to forestall, prior to Ranbaxy's agreed-upon November 30, 2011 entry date, judicial decisions that the Unasserted Formulation Patents were invalid and/or not infringed.

1. Apotex

282. For instance, after it received a Paragraph IV certification in December of 2008 from Apotex, Inc. and Apotex Corporation ("Apotex") as to the '995 Patent, the Unasserted Formulation

Patents, and the '156 Patent, the Pfizer Defendants sued Apotex for infringement of only the '995 Patent. Apotex's answer included counterclaims, pursuant to 21 U.S.C. § 355(j)(5)(C), asserting non-infringement and invalidity of the '995 Patent (and '667 reissue Patent), the Unasserted Formulation Patents, and the '156 Patent.

283. As the Apotex trial court recognized: "Apotex's hope is to obtain a decision from this Court that the Unasserted Patents are invalid or are not infringed by Apotex's product, thereby triggering Ranbaxy's exclusivity period. Absent such a court ruling (either in this case or in litigation involving another subsequent ANDA filer), Apotex will not be able to market its generic atorvastatin drug until 180 days after Ranbaxy begins marketing its drug, which, as a result of the settlement agreement between Pfizer and Ranbaxy, will not occur until November 2011 at the earliest."

284. In furtherance of the Agreement, the Pfizer Defendants sought dismissal of Apotex's counterclaims, arguing that they were nonjusticiable.

285. Although the Apotex court eventually denied the Pfizer Defendants' motion to dismiss, the motion had its intended effect: it delayed discovery and litigation for well over a year and, combined with subsequent litigation delay tactics surrounding discovery and summary judgment motions, prevented Apotex from obtaining a judgment of non-infringement and invalidity of the Unasserted Formulation Patents and the '156 Patent before November 30, 2011.

2. Mylan

286. On May 1, 2009, Mylan sent the Pfizer Defendants a letter providing notice of Mylan's ANDA submission and intent to market a generic version of Lipitor, supplying a Paragraph IV certification as to the Unasserted Formulation Patents and the '156 Patent, and offering confidential access to certain portions of Mylan's ANDA. By June 15, 2009, the Pfizer

Defendants had filed an action against Mylan alleging infringement of only the '156 Patent, and seeking a declaratory judgment of infringement of the Process Patents.

287. Mylan filed a motion for leave to file an amended answer containing counterclaims pertaining to the Unasserted Formulation Patents, to obtain a declaration of noninfringement and/or invalidity with respect to them. In support of that effort, Mylan sought discovery regarding the Unasserted Formulation Patents. Mylan's motion to compel discovery was granted by court order on August 25, 2010.

288. But the Pfizer Defendants continued to refuse to supply Mylan with the discovery it required. Mylan was forced to file an emergency motion to enforce the court's discovery order.

289. To try to sabotage Mylan's continued efforts to obtain discovery and thus proceed with its counterclaims pertaining to the Unasserted Formulation Patents, the Pfizer Defendants, on August 30, 2010, hastily covenanted not to sue Mylan, hoping to moot Mylan's continued efforts to discover facts that would assist its counterclaims and the court's order of August 25, 2010 compelling that discovery.

290. The court expressed frustration with the Pfizer Defendants' litigation tactics regarding the Unasserted Formulation Patents, and enforced its order requiring the Pfizer Defendants to supply discovery to Mylan pertaining to the Unasserted Patents:

> I'm granting Mylan's request. I'm very troubled by the conduct of Pfizer here with respect to this ongoing discovery dispute. The way I see it, if Pfizer wanted to provide a covenant not to sue, it was within its authority at any time to provide the covenant not to sue with respect to the formulation patents. For whatever reasoning only known to Pfizer, they waited until August 30th [2010] to give the covenants not to sue, which was perhaps not coincidently shortly after the issuance of the August 25th order granting the defendants' request for discovery. . . . That's simply just not how this is supposed to work.

291. The Pfizer Defendants continued to delay the progress of the case. In a November 20, 2010 letter to the court regarding Dr. Reddy's Laboratories Ltd.'s ("DRL") request to be heard

at the *Markman* hearing in the Mylan patent litigation pertaining to the '156 Patent, counsel for Mylan complained about the Pfizer Defendants' continued dilatory tactics: "Pfizer uses DRL's request to be heard on the '156 patent as another opportunity to attempt to delay the Pfizer-Mylan cases."

292. Mylan also sought to remove Ranbaxy's blocking 180-day exclusivity period by way of a separate action against the FDA seeking an order requiring the FDA to determine whether or not Ranbaxy was entitled to a 180-day first-to-file marketing exclusivity.

3. Actavis

293. In August of 2010, the Pfizer Defendants sued Actavis Group hf, Actavis Inc., Actavis Elizabeth LLC and Actavis Pharma Manufacturing Private Ltd. (collectively "Actavis") after Actavis submitted to the FDA an ANDA seeking approval to market generic Lipitor. Although Actavis had included the Unasserted Formulation Patents in its Paragraph IV certification, the Pfizer Defendants sued Actavis only for infringement of the '156 Patent.

294. In September 2010, Actavis counterclaimed for declaratory judgment of invalidity and non-infringement of the Unasserted Formulation Patents. The Pfizer Defendants moved to dismiss these counterclaims as unripe. In opposing that motion, Actavis argued that "Pfizer's listing of the [Unasserted Formulation Patents] in the Orange Book and its refusal to litigate them creates patent uncertainty and indefinitely delays the approval of Actavis' ANDA," and noted that "[e]ven if Pfizer granted Actavis a covenant not to sue on the [Unasserted Formulation Patents], however, it would not address the fact that Actavis is suffering from an indefinite delay in FDA approval of its ANDA and its concurrent inability to enter the market."

295. Actavis also argued that, by virtue of the Pfizer Defendants' Agreement with Ranbaxy and its refusal to litigate the validity and infringement of its Unasserted Formulation

Patents, "Actavis is being restrained from the free exploitation of non-infringing goods, it is suffering exactly the type of injury-in-fact that is sufficient to establish Article III standing" (internal citations and quotations omitted).

296. Despite their efforts to do so, no ANDA filer was able to circumvent the Agreement between the Pfizer Defendants and Ranbaxy by triggering Ranbaxy's 180-day marketing exclusivity prior to November 30, 2011.

K. Ranbaxy's ANDA Would Have Been Approved Earlier Absent Defendants' Anticompetitive Scheme

297. Ranbaxy's atorvastatin calcium ANDA would have received final approval earlier absent the Defendants' anticompetitive conduct. The FDA has policies and procedures in place to prioritize the review of ANDAs, *e.g.*, expediting the review of the first applications for which there are no blocking patents or exclusivities. Regarding the FDA's review of applications for generic Lipitor, the Agreement blocked the applicants, including Ranbaxy, from marketing their products. The FDA was aware that the earliest date that Ranbaxy could market generic Lipitor under its Agreement with Pfizer was November 30, 2011. As Ranbaxy maintained the 180-day exclusivity, all subsequent applicants were blocked from marketing generic Lipitor as well, until Ranbaxy's exclusivity was triggered and had expired.

298. Furthermore, the FDA was under tremendous pressure, including from Congress, to speed consumer access to generic Lipitor at the earliest possible moment. Ranbaxy was also under tremendous pressure to monetize its biggest asset, *i.e.*, its first-to-file atorvastatin ANDA, at the earliest possible moment, so much so that Ranbaxy paid Teva a large amount of money -- in effect an insurance policy -- to ensure that Ranbaxy would be able to launch generic Lipitor at the earliest possible moment.

299. As it turned out, Ranbaxy was granted final approval on November 30, 2011, *i.e.*, it was able to launch on the earliest date under the Agreement with the Pfizer Defendants. Ranbaxy shipped generic Lipitor slightly in advance of that date, under "quarantine" agreements with wholesalers. Had the Agreement permitted an earlier entry date, or had there been no such Agreement at all, generic Lipitor could have been, and would have been, marketed earlier than November 30, 2011, because the FDA would have granted final approval earlier and Ranbaxy would have launched earlier.

300. The FDA did not earlier issue its formal written denial of Pfizer's Petition until November 30, 2011 for the same reason: the FDA knew from Ranbaxy that the Agreement prevented Ranbaxy from coming onto the market until November 30, 2011. Thus, there was no need for the FDA to issue the formal written denial of Pfizer's Petition earlier than November 30, 2011.

1. The Longstanding FDA Policy of Prioritizing the Review of ANDAs

301. As a matter of procedure and practice, the FDA has long prioritized its review of pending applications. For example, in 1990 the Division of Generic Drugs within the FDA issued a policy and procedure guide establishing a "first-in, first-reviewed" policy for generic drug applicants. This policy, along with similar guidance for the pharmaceutical industry, has been updated and modified from time to time and is still in place today. One of the modifications that has been instituted over the years is to prioritize the review of the first ANDAs for which there is no blocking patent or exclusivity.

302. Similarly, the FDA has been experiencing a backlog of pending applications, such that prioritizing ANDA review is more important than ever. As a matter of procedure and practice, in a situation where an ANDA filer will not be able to market a drug until a time far into the future,

such as Ranbaxy's generic Lipitor ANDA due to the Agreement, the FDA shifts assets to other priorities within the Office of Generic Drugs. The FDA prioritizes the review of ANDAs in this way by keeping abreast of the current posture of any litigation that may impact the timing of approval of an ANDA. For instance, as a matter of procedure and practice, upon accepting an ANDA for filing, the FDA expressly requests that the applicant promptly submit a copy of any settlement agreement between the applicant and the patent holder.

2. The FDA's Review of Ranbaxy's ANDA for Atorvastatin Calcium

303. On June 18, 2008, Ranbaxy announced the Agreement in which Ranbaxy's launch date was delayed until November 30, 2011. Ranbaxy submitted this information to the FDA shortly thereafter.

304. Thus, due to the FDA's longstanding policy of prioritizing the review of ANDAs and the recent pressure of the ANDA backlog, on information and belief, once the FDA learned of the fact that the first generic for Lipitor, *i.e.*, Ranbaxy, would not be marketed until November 30, 2011, the FDA shifted assets away from Ranbaxy's ANDA and the Petition and toward other priorities within the FDA until the November date drew closer.

3. The Tremendous Pressure on the FDA to Approve Generic Lipitor

305. That the FDA was under immense pressure to approve a generic Lipitor product also shows that it would have earlier approved Ranbaxy's ANDA absent the agreed-to date for Ranbaxy's market entry contained in the Agreement.

306. For example, on March 10, 2011, Senate Health, Education, Labor, and Pensions Committee Chairman Tom Harkin, along with Senators Jay Rockefeller, Charles Schumer, Debbie Stabenow, and Sherrod Brown sent a letter to FDA Commissioner Dr. Margaret Hamburg. In the letter, the Senators stated: "Given the tremendous savings that access to generic atorvastatin will

afford both consumers and the government, we urge you to act now to clarify the relevant regulatory issues in the matter so the public can receive access to a more affordable generic version of Lipitor on the earliest possible date." The "tremendous savings" to consumers and the government would be between "$3.97 billion to $6.7 billion a year upon generic entry, which equates to $10.9 million to $18.3 million a day." Likewise, the FDA recognized the importance and cost savings of having a generic Lipitor available to consumers.

4. The Tremendous Pressure on Ranbaxy to Market a Generic Lipitor and/or Otherwise Monetize its First-To-File Exclusivity

307. Ranbaxy, too, was motivated to monetize its first-to-file 180-day marketing exclusivity and would have more rapidly pursued its atorvastatin calcium ANDA absent the agreed-to date for Ranbaxy's market entry contained in the Agreement.

308. The first-to-file generic Lipitor was a tremendous opportunity for Ranbaxy. Despite being on the market with a generic Lipitor for only one month in 2011, atorvastatin calcium was Ranbaxy's largest selling product in 2011. Ranbaxy also achieved sales growth of 17% over the previous year, "mainly on account of revenues from First to File product, Atorvastatin, in the US market in December 2011."

309. In order to capitalize on the first to file opportunity, Ranbaxy took steps to insure that issues related to its good manufacturing practices did not prevent it from being able to market generic Lipitor. For instance, on information and belief, in December 2009, Ranbaxy effectuated a manufacturing site transfer of atorvastatin calcium from its facility in India to Ranbaxy's wholly-owned subsidiary, Ohm Laboratories in New Jersey. Whatever issues Ranbaxy may have been having with FDA regulatory compliance at one or more of its facilities in India did not affect the Ohm facility in New Jersey. This is borne out by the fact that Ranbaxy ultimately received approval to market generic Lipitor in the U.S. from the Ohm facility in New Jersey.

310. Absent the Defendants' anticompetitive scheme, Ranbaxy could and would have proceeded with a manufacturing site transfer earlier, either to Ohm or to another facility. On information and belief, the Ohm facility had been operational for Ranbaxy for quite some time and was available to take over manufacturing of generic atorvastatin calcium pursuant to a site transfer at any time during the relevant time period at issue here.

311. In fact, at or around the same time Ranbaxy filed its ANDA for atorvastatin calcium, Ranbaxy also filed the first ANDA to market a generic version of simvastatin, a drug in the same "statin" family as atorvastatin calcium. On information and belief, as with atorvastatin, Ranbaxy effectuated a manufacturing site transfer for simvastatin from India to the Ohm facility in New Jersey. Ranbaxy received final approval for its simvastatin ANDA on June 23, 2006 and began marketing its first-to-file generic shortly thereafter.

312. Similarly, on information and belief, in the same time period as the atorvastatin calcium filing, Ranbaxy filed the first ANDA with the FDA to market donepezil hydrochloride. Donepezil hydrochloride is the active ingredient in Aricept. On information and belief, Aricept had approximately $2.6B in sales in 2010. On information and belief, around the time of the atorvastatin calcium site transfer in December 2009, Ranbaxy effectuated a site transfer of donepezil hydrochloride from India to the Ohm facility in New Jersey. On information and belief, on the first day a generic could be marketed, November 26, 2010, Ranbaxy received approval with first-to-file exclusivity to market donepezil hydrochloride. In 2011, donepezil was the second best performing product after atorvastatin calcium.

313. Finally, on information and belief, Ranbaxy and Teva entered into an agreement to insure that Ranbaxy was able to benefit from its first-to-file status. Negotiations between Ranbaxy and Teva regarding generic Lipitor began in 2009. On information and belief, Ranbaxy and Teva

discussed three possible ways of monetizing Ranbaxy's first to file ANDA: (1) a manufacturing site transfer from Ranbaxy's facility in India to Teva, under which Teva would pay Ranbaxy a lump sum transfer fee and royalties on sales of generic Lipitor; (2) a simultaneous launch of generic Lipitor by Ranbaxy and Teva; and (3) a manufacturing site transfer from India to Ranbaxy's Ohm facility in New Jersey, Ranbaxy's return to Teva of the lump sum transfer fee, and Ranbaxy's payment of a portion of its profits on generic Lipitor to Teva. In 2010, Ranbaxy and Teva signed an agreement regarding generic Lipitor containing some or all of these options and/or other options.

314. Once Ranbaxy made the decision to partner with another company in order to monetize generic Lipitor, it is hardly surprising Ranbaxy chose Teva. It is well known in the industry that Teva looks to partner with 180-day exclusivity holders given the profit opportunity such exclusivities present.

315. Since Ranbaxy gained approval to market generic Lipitor from its Ohm facility in New Jersey, on information and belief, it never needed the insurance policy that the deal with Teva effectively provided. However, Ranbaxy still paid Teva a substantial amount of money to insure that it would be able to monetize its first-to-file atorvastatin calcium ANDA at the earliest possible moment under the Agreement

VI. TRADE AND COMMERCE

316. Defendants' efforts to monopolize and restrain competition in the market for atorvastatin calcium have substantially affected interstate commerce.

317. At all material times, the Pfizer Defendants manufactured, promoted, distributed, and sold substantial amounts of branded Lipitor in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States. Beginning around November 30, 2011, Ranbaxy did the same with respect to generic Lipitor.

VII. MONOPOLY POWER AND MARKET DEFINITION

318. At all relevant times, the Pfizer Defendants had monopoly power over atorvastatin calcium because they had the power to maintain the price of atorvastatin calcium at supracompetitive levels without losing substantial sales.

319. A small but significant, non-transitory price increase by the Pfizer Defendants with respect to Lipitor would not have caused a significant loss of sales.

320. Lipitor does not exhibit significant, positive cross-elasticity of demand with respect to price, with any product other than AB-rated generic versions of Lipitor.

321. Because of, among other reasons, its use and varying ability to inhibit the production of cholesterol, Lipitor is differentiated from all products other than AB-rated generic versions of Lipitor.

322. The Pfizer Defendants needed to control only Lipitor and its AB-rated generic equivalents, and no other products, in order to maintain the price of Lipitor profitably at supracompetitive prices. Only the market entry of a competing, AB-rated generic version of Lipitor would render the Pfizer Defendants unable to profitably maintain their current prices of Lipitor without losing substantial sales.

323. The Pfizer Defendants also sold branded Lipitor at prices well in excess of marginal costs, and in excess of the competitive price, and enjoyed high profit margins.

324. Defendants have had, and exercised, the power to exclude generic competition to branded Lipitor.

325. Defendants, at all relevant times, enjoyed high barriers to entry with respect to branded and generic Lipitor.

326. To the extent that Plaintiffs are legally required to prove monopoly power

circumstantially by first defining a relevant product market, Plaintiffs allege that the relevant market is all atorvastatin calcium products -- *i.e.*, Lipitor (in all its forms and dosage strengths) and AB-rated bioequivalent atorvastatin calcium products. During the period relevant to this case, Defendants have been able to profitably maintain the price of Lipitor well above competitive levels.

327. The relevant geographic market is the United States and its territories.

328. The Pfizer Defendants' market share in the relevant market was 100% until the entry of generic atorvastatin calcium in late November 2011.

VIII. MARKET EFFECTS

329. Ranbaxy began to ship generic Lipitor on or shortly before November 29, 2011, prior to receiving formal, written final approval of its ANDA from the FDA. Ranbaxy informed its customers that such shipments of generic Lipitor were subject to "quarantine," meaning that the generic Lipitor could not be resold until the FDA's issuance to Ranbaxy of formal, written ANDA approval.

330. The FDA purposely waited to issue formal written approval for Ranbaxy's ANDA until November 30, 2011, because the FDA knew that the Agreement prevented Ranbaxy from selling generic Lipitor until November 30, 2011. Ranbaxy's ANDA was in an approvable condition well before November 30, 2011 and, were it not for the Agreement, would have received final FDA approval at an earlier time. The FDA organizes its priorities around "rate limiters," and the Agreement was a rate limiter that caused the FDA to wait until November 30, 2011 to issue formal, written approval to Ranbaxy's ANDA.

331. The acts and practices of Defendants had the purpose and effect of unreasonably restraining and injuring competition by protecting Lipitor from generic competition for a substantial period of time until November 30, 2011. Defendants' actions allowed the Pfizer

Defendants to maintain a monopoly and exclude competition in the market for atorvastatin calcium, to the detriment of Plaintiffs.

332. In the absence of some or all of Defendants' overarching anticompetitive scheme, Ranbaxy or one or more other generic competitors would have begun selling AB-rated generic versions of Lipitor much sooner than November 30, 2011, when Ranbaxy launched. Specifically, in the absence of some or all of Defendants' overarching anticompetitive scheme, Ranbaxy or one or more generic competitors would have launched generic Lipitor earlier than they did.

333. Ranbaxy and the other ANDA applicants seeking to market generic Lipitor had extensive experience in the pharmaceutical industry, including in obtaining approval for ANDAs, manufacturing commercial launch quantities adequate to meet market demand, marketing generic pharmaceutical products, and paying and receiving consideration for selective waiver and/or relinquishment of 180-day first-to-file marketing exclusivities.

334. As a result of the delay in generic Lipitor competition brought about by Defendants' overarching anticompetitive scheme, in whole or in part, Plaintiffs paid more to acquire atorvastatin calcium than they would have paid absent Defendants' illegal conduct.

335. Typically, generic versions of brand-name drugs are initially priced significantly below the corresponding branded drug to which they are AB-rated. As a result, upon generic entry, some or all of the direct purchases of branded drugs are rapidly substituted for generic versions of the drug. As more generic manufacturers enter the market, prices for generic versions of a drug predictably plunge even further because of competition among the generic manufacturers, and, correspondingly, the brand name drug continues to lose even more market share to the generics.

336. This price competition enables all direct purchasers of the drugs to: (a) purchase

generic versions of a drug at a substantially lower price, and/or (b) purchase the brand name drug at a reduced price. Consequently, brand name drug manufacturers have a keen financial interest in delaying the onset of generic competition, and purchasers experience substantial cost inflation from that delay.

337. If generic Lipitor competitors had not been unlawfully prevented from earlier entering the market and competing with the Pfizer Defendants, Plaintiffs would have paid less for atorvastatin calcium by (a) substituting purchases of less-expensive AB-rated generic Lipitor for their purchases of more-expensive branded Lipitor, (b) receiving discounts on their remaining branded Lipitor purchases, and (c) purchasing generic Lipitor at lower prices sooner.

338. Moreover, due to Defendants' conduct, other generic manufacturers were discouraged from and/or delayed in developing generic versions of Lipitor.

339. Thus, Defendants' unlawful conduct deprived Plaintiffs of the benefits of competition that the antitrust laws were designed to ensure.

IX. ANTITRUST IMPACT

340. During the relevant period, Plaintiffs (or their assignors) purchased substantial amounts of Lipitor from the Pfizer Defendants. After generic entry, Plaintiffs purchased substantial amounts of generic atorvastatin. As a result of Defendants' illegal conduct, Plaintiffs were compelled to pay, and did pay, artificially inflated prices for their atorvastatin calcium requirements. Those prices were substantially greater than the prices that would have been paid absent the illegal conduct alleged herein, because: (1) the price of brand-name Lipitor was artificially inflated by Defendants' illegal conduct, and/or (2) Plaintiffs were deprived of the opportunity to purchase lower-priced generic Lipitor sooner.

341. As a consequence, Plaintiffs have sustained substantial losses and damage to their

business and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial.

X. CLAIMS FOR RELIEF

CLAIM I: VIOLATION OF 15 U.S.C. § 2
(MONOPOLIZATION AND MONOPOLISTIC SCHEME)

342. Plaintiffs hereby incorporate by reference the allegations contained in paragraphs 1 through 341 above. This claim is asserted against the Pfizer Defendants only.

343. At all relevant times, the Pfizer Defendants possessed substantial market power (*i.e.*, monopoly power) in the relevant market. The Pfizer Defendants possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

344. Through the overarching anticompetitive scheme, as alleged extensively above, the Pfizer Defendants willfully maintained their monopoly power in the relevant market using restrictive or exclusionary conduct, rather than by means of greater business acumen, and injured Plaintiffs thereby.

345. It was the Pfizer Defendants' conscious object to further their dominance in the relevant market by and through the overarching anticompetitive scheme.

346. As a direct and proximate result of the Pfizer Defendants' illegal and monopolistic conduct, as alleged herein, Plaintiffs suffered antitrust injury as alleged above.

CLAIM II: VIOLATION OF 15 U.S.C. § 1
(CONSPIRACY IN RESTRAINT OF TRADE)

347. Plaintiffs hereby incorporate by reference the allegations contained in paragraphs 1 through 341 above. This claim is asserted against all Defendants.

348. In 2008, the Pfizer Defendants and Ranbaxy entered into the Agreement, and Ranbaxy thereby joined the Pfizer Defendants' overarching anticompetitive scheme as a

co-conspirator. The Agreement is and was a contract, combination and/or conspiracy that substantially, unreasonably, and unduly restrained trade in the relevant market, the purpose and effect of which was to: (a) allocate all sales of atorvastatin calcium in the United States to the Pfizer Defendants until November 30, 2011; (b) prevent the sale of any generic version of atorvastatin calcium in the United States until November 30, 2011; and (c) fix the price which Plaintiffs would pay for atorvastatin calcium.

349. The Agreement harmed Plaintiffs as set forth above.

350. The Agreement covered a sufficiently substantial percentage of the relevant market to harm competition.

351. The Pfizer Defendants and Ranbaxy are each *per se* liable for the creation, maintenance, and enforcement of the Agreement.

352. Alternatively, the Pfizer Defendants and Ranbaxy are liable for the Agreement under a "quick look" and/or rule of reason standard.

353. There is and was no legitimate, nonpretextual, procompetitive business justification for the Agreement that outweighs its harmful effect. Even if there was some conceivable justification, the Agreement is and was broader than necessary to achieve such a purpose.

354. As a direct and proximate result of the Pfizer Defendants' and Ranbaxy's anticompetitive conduct, Plaintiffs suffered antitrust injury as alleged above.

CLAIM III: VIOLATION OF 15 U.S.C. § 2 (CONSPIRACY TO MONOPOLIZE)

355. Plaintiffs hereby incorporate by reference the allegations in paragraphs 1 through 341 above. This claim is asserted against all Defendants.

356. Through the overarching anticompetitive scheme, as alleged extensively above, the Pfizer Defendants and Ranbaxy conspired to maintain and enhance the Pfizer Defendants' monopoly power in the relevant market.

357. The Pfizer Defendants and Ranbaxy knowingly and intentionally conspired to maintain and enhance the Pfizer Defendants' monopoly power in the relevant market.

358. The Pfizer Defendants and Ranbaxy specifically intended that the overarching anticompetitive scheme would maintain the Pfizer Defendants' monopoly power in the relevant market, and injured Plaintiffs thereby.

359. The Pfizer Defendants and Ranbaxy each committed at least one overt act in furtherance of the conspiracy.

360. As a direct and proximate result of the Pfizer Defendants' and Ranbaxy's illegal and monopolistic conduct, Plaintiffs suffered antitrust injury as alleged above.

CLAIM IV: VIOLATION OF 15 U.S.C. § 2
(ATTEMPTED MONOPOLIZATION)

361. Plaintiffs hereby incorporate by reference the allegations in paragraphs 1 through 341 above. This claim is asserted against the Pfizer Defendants only.

362. The Pfizer Defendants, through their overarching anticompetitive scheme, specifically intended to maintain monopoly power in the relevant market. It was the Pfizer Defendants' conscious objective to control prices and/or to exclude competition in the relevant market.

363. The natural and probable consequence of the Pfizer Defendants' overarching anticompetitive scheme, which was intended by, and plainly foreseeable to, the Pfizer Defendants, was to control prices and exclude competition in the relevant market, to the extent it did not succeed.

364. There was a substantial and real chance, a reasonable likelihood, and/or a dangerous probability that the Pfizer Defendants would succeed in and achieve its goal of maintaining monopoly power in the relevant market.

365. As a direct and proximate result of the Pfizer Defendants' illegal and monopolistic conduct, Plaintiffs suffered antitrust injury as alleged above.

XI. DEMAND FOR JUDGMENT

WHEREFORE, Plaintiffs pray for judgment against Defendants and for the following relief:

A. Joint and several judgments against Defendants and in favor of Plaintiffs;

B. An award to Plaintiffs of three times their actual damages, as determined by a jury trial;

C. Permanent injunctive relief enjoining Defendants from continuing their unlawful conduct and requiring them to take affirmative steps to dissipate the effects of their prior conduct;

D. An award to Plaintiffs of the costs of this suit, including reasonable attorneys' fees as provided by law; and

E. Such other and further relief as the Court deems just and appropriate.

XII. JURY DEMAND

Plaintiffs demand a trial by jury of all issues so triable.

Dated: December 11, 2012

Respectfully submitted,

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